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No. ——

Supreme Court, U.S.
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IN THE

Supreme Court of the United States

OCTOBER TERM, 1992

NATIONAL KIDNEY PATIENTS ASSOCIATION, *et al.*,
Petitioners,

v.

LOUIS W. SULLIVAN, M.D., SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, and WILLIAM L. ROPER, M.D., ADMINISTRATOR OF THE UNITED STATES HEALTH CARE FINANCING ADMINISTRATION,
Respondents.

Petition for a Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

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PETITION FOR A WRIT OF CERTIORARI

JOEL I. KLEIN *
PAUL M. SMITH
RICHARD G. TARANTO
KLEIN, FARR, SMITH & TARANTO
2550 M Street, N.W.
Washington, D.C. 20037
(202) 775-0184
* *Counsel of Record*

WILSON - EPES PRINTING CO., INC. - 789-0096 - WASHINGTON, D.C. 20001

QUESTION PRESENTED

Whether Medicare claimants must exhaust administrative remedies before pursuing a judicial challenge to generally applicable rules and regulations governing the "method" by which benefits are determined.

TABLE OF CONTENTS

	Page
QUESTION PRESENTED	i
TABLE OF AUTHORITIES	iv
OPINIONS BELOW	2
JURISDICTION	2
STATUTE INVOLVED	2
STATEMENT	2
1. Legal and Factual Background	3
2. Proceedings on the Preliminary Injunction	5
3. Proceedings on the Government's Claim for Refund	7
REASONS FOR GRANTING THE PETITION	8
I. THE D.C. CIRCUIT'S DECISION CONTRAVENES THIS COURT'S DEFINITIVE INTERPRETATION OF SECTION 1395ff(b)(1)(C), WHICH WAS NOT OVERTURNED BY THE SUBSEQUENT AMENDMENT TO THAT PROVISION	10
II. THE INTERCIRCUIT CONFLICT REGARDING THE SCOPE OF SECTION 1395ff(b)(1)(C) SHOULD BE RESOLVED NOW	19
CONCLUSION	22

TABLE OF AUTHORITIES

Cases — Page

Association of Seat Lift Manufacturers v. Bowen, 858 F.2d 308 (6th Cir. 1988), *cert. denied*, 489 U.S. 1078 (1989) 19
Blue Bell Medical, Inc. v. Pennsylvania Blue Shield, 775 F. Supp. 829 (M.D. Pa. 1991) 21
Bodimetric Health Servs., Inc. v. Aetna Life & Cas., 903 F.2d 480 (7th Cir.), *cert. denied*, 111 S. Ct. 579 (1990) 15, 19, 20
Bowen v. Michigan Academy of Family Physicians, 476 U.S. 667 (1986) ..... *passim*
Colorado Clinical Labs, Inc. v. Newman, 1990 Medicare and Medicaid Guide (CCH) ¶ 39,056 (N.D. Tex. 1990) 21
Griffith v. Bowen, 678 F. Supp. 942 (D. Mass. 1988) 21
Health Indus. Distribs. Ass'n v. Bowen, 1987 Medicare and Medicaid Guide (CCH) ¶ 36,748 (D.D.C. 1987) 21
Heckler v. Ringer, 466 U.S. 602 (1984) ..... *passim*
Isaacs v. Bowen, 865 F.2d 468 (2d Cir. 1989) 10, 19
Kuritzky v. Blue Shield, 850 F.2d 126 (2d Cir. 1988), *cert. denied*, 488 U.S. 1006 (1989) 19, 20
McCuin v. Secretary of Health and Human Servs., 817 F.2d 161 (1st Cir. 1987) 15, 19, 20
Medical Fund-Philadelphia Geriatric Center v. Heckler, 804 F.2d 33 (3d Cir. 1986) 14, 20
Outpatient Ophthalmic Surgery Society, Inc. v. Sullivan, 1990 Medicare and Medicaid Guide (CCH) ¶ 38,981 (D.D.C. 1990) 21
Oxygen Equip. Co. v. Sullivan, 1989 Medicare and Medicaid Guide (CCH) ¶ 37,989 (N.D. Ala. 1989), *aff'd without opinion*, 914 F.2d 268 (11th Cir. 1990) 21
Pulmocare Pharmacy, Inc. v. Sullivan, 1992 Medicare and Medicaid Guide (CCH) ¶ 40,387 (D. Or. 1992) 21, 22
Roen v. Sullivan, 764 F. Supp. 555 (D. Minn. 1991) 21
Texas Medical Ass'n v. Sullivan, 875 F.2d 1160 (5th Cir.), *cert. denied*, 493 U.S. 1011 (1989) 19, 20

TABLE OF AUTHORITIES—Continued

Page

United States v. Erika, Inc., 456 U.S. 201 (1982) ..*passim*
University of Texas v. Camenisch, 451 U.S. 390 (1981) 6
Vorster v. Bowen, 709 F. Supp. 934 (C.D. Cal. 1989) 21

Statutory Provisions

28 U.S.C. § 1331 ..... 5, 13, 14
42 U.S.C. § 1395ff(b) ..... *passim*
§ 1395rr ..... *passim*
§ 1395u ..... *passim*
Omnibus Budget Reconciliation Act, Pub. L. No. 99-509, § 9341(a)(1)(D), 100 Stat. 2038 (1986) (codified at 42 U.S.C. § 1395ff(b)(4)) 17
Omnibus Budget Reconciliation Act, Pub. L. No. 101-239, § 6203(b)(1), 103 Stat. 2106 (1989), amending 42 U.S.C. § 1395rr(b)(7) 6
Social Security Act, 42 U.S.C. § 300, *et seq.* 11

Legislative Materials

H.R. Conf. Rep. No. 1012, 99th Cong., 2d Sess. (1986), reprinted in 1986 U.S.C.C.A.N. 3868.... 16, 18
H.R. Rep. No. 727, 99th Cong., 2d Sess. (1986), reprinted in 1986 U.S.C.C.A.N. 3607 16
Hearings on S. 1158 Before the Subcommittee on Health of the Senate Committee on Finance, 99th Cong., 1st Sess. (1985) 17
131 Cong. Rec. 22267 (1985) 17
29833 (1985) 17
132 Cong. Rec. 25941 (1986) 17
32978 (1986) 18
32979 (1986) 18
33313 (1986) 18

Regulations

42 C.F.R. § 405.502(a)(7) 4
§ 405.701 10
§ 405.801 10
§ 405.860 11
§ 408.108(c) 11
51 Fed. Reg. 29,404 (1986) 4

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PETITION FOR A WRIT OF CERTIORARI

Petitioners National Kidney Patients Association, *et al.*, respectfully request that a writ of certiorari issue to review the judgment of the United States Court of Appeals for the District of Columbia Circuit.[1]

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[1] The other petitioners are Robert Rosen, Robert D. Meyers, Ellen Lyons, Paul Feinsmith, Thomas Bien, Clarence L. Steffan, Mary Anne Freeland, Flossie Reed, Dr. Everett Radovsky, Carl Chopinsky, and Home Intensive Care, Inc., which has no parent corporation and one non-wholly owned subsidiary, Gynesis Health Care, Inc.

OPINIONS BELOW

The opinion of the court of appeals is reported at 958 F.2d 1127 and reprinted in the Appendix ("Pet. App.") at 1a-22a. The opinion of the district court is reported at 754 F. Supp. 900 and reprinted at Pet. App. 23a-35a. An earlier opinion of the court of appeals is reported at 902 F.2d 51 and reprinted at Pet. App. 36a-42a. An earlier bench ruling of the district court is unreported and reprinted at Pet. App. 43a-58a.

JURISDICTION

The judgment of the court of appeals was entered on March 13, 1992, and a timely petition for rehearing was denied on June 1, 1992. On July 29, 1992, Chief Justice Rehnquist extended the time for filing a petition until September 29, 1992. This Court's jurisdiction is invoked pursuant to 28 U.S.C. § 1254(1).

STATUTE INVOLVED

The section of the Medicare statute at issue in this case, 42 U.S.C. § 1395ff(b)(1)(C), provides: "Any individual dissatisfied with any determination under subsection (a) of this section as to . . . the amount of benefits under part A or part B of this subchapter (including a determination where such amount is determined to be zero), . . . shall be entitled to a hearing thereon by the Secretary to the same extent as is provided in section 405(b) of this title and to judicial review of the Secretary's final decision after such hearing as is provided in section 405(g) of this title."

STATEMENT

Petitioners seek review of a D.C. Circuit decision holding that the Medicare statute requires exhaustion of administrative remedies before a claimant can obtain judicial review of a generally applicable rule or

regulation governing the "method" by which benefits are determined.

1. *Legal and Factual Background.* In 1972 Congress amended the Medicare statute to provide coverage under part B of the program (non-hospital services) for patients who need renal dialysis as a result of permanent kidney failure. 42 U.S.C. § 1395rr. The statute established two different methodologies for determining the federal government's payment obligation: Method I covered treatment conducted at, or supervised by, a federally certified dialysis clinic (§ 1395rr(b)(1)(A)); and Method II covered the equipment and supplies necessary for home treatment by the patient (§ 1395rr(b)(1)(B)). The reimbursement rate for Method I services was set at 80% of a regionally adjusted, national "composite" rate (42 U.S.C. § 1395rr(b)(7)), to be determined by the federal Health Care Financing Administration ("HCFA"), an agency within the United States Department of Health and Human Services ("HHS"). The rate for Method II services was set at 80% of a "reasonable charge" (42 U.S.C. § 1395u(b)(3)), to be determined by each local private insurance carrier that, pursuant to 42 U.S.C. § 1395u, administers part B of the Medicare program under contract with HHS.

The overwhelming majority of dialysis patients receive clinic-based care covered by Method I, even though, as the district court found in this case, "home dialysis is less risky and less disruptive." Pet. App. 25a. Home-based care is more difficult to arrange because it requires someone to assist the patient when inserting the needles, and to monitor and adjust the equipment during the 12-15 hours per week that dialysis normally requires. C.A. App. 225, 230, 244. To address this need, petitioner Home Intensive Care, Inc. ("HIC"), established a program that provides a nurse or technician to help the patient administer home treatment. HIC began operations in 1985 and, during the time relevant here, was

providing services to more than 1000 Medicare-covered dialysis patients. Pet. App. 4a, 24a.

Blue Cross and Blue Shield of Florida, which is the private carrier that administers the Medicare program in that State, was responsible for processing the large majority of HIC's claims. C.A. App. 19. Blue Cross had set its Method II rate, prior to HIC's existence, at $3100 per month. Pet. App. 46a. This rate, while similar to the Method II home-dialysis rate adopted by other carriers throughout the country (C.A. App. 83-84), was almost twice HCFA's Method I rate for clinic dialysis. *See* 51 Fed. Reg. 29,404, *et seq.* (Aug. 15, 1986). Dissatisfied with this differential, HCFA made repeated attempts to have Congress eliminate the Method II statutory option, but Congress rejected those efforts. Pet App. 52a; C.A. App. 32.

Faced with legislative inaction, HCFA decided to take action on its own. On February 25, 1988, without notice or an opportunity for public comment, it issued "Transmittal 1237," instructing the private carriers nationwide to review their Method II (home care) rates and requiring them "in effect [to] limit[] reimbursements for home dialysis treatments to the Method I level." Pet. App. 25a; *see id.* at 48a-50a. The carriers immediately did as instructed, uniformly bringing their home-care rates under Method II into conformity with HCFA's Method I clinic rate. C.A. App. 84. Blue Cross, for example, announced that it had determined that its Method II rate was not "inherently reasonable" (*see* 42 C.F.R. § 405.502(a)(7)), and that it therefore intended to reduce the rate from $3100 to $1625 per month, effective January 1, 1989. Pet. App. 4a. Blue Cross initiated this action without conducting any analysis of actual costs (*id.* at 51a); and it proposed this lower rate for Medicare patients even though it continued to pay the $3100 rate for home dialysis under its private insurance programs (C.A. App. 621-22).

2. *Proceedings on the Preliminary Injunction.* On November 9, 1988, petitioner HIC, joined by the National Kidney Patients Association and 10 individuals who were using HIC's home-dialysis services, filed suit against HHS, HCFA, and Blue Cross in the district court for the District of Columbia. The complaint, asserting jurisdiction under 28 U.S.C. § 1331, challenged the legality of defendants' actions in modifying the Method II rate for home dialysis and sought, *inter alia*, a preliminary injunction barring the new rate from taking effect. On December 22, 1988, after a three-day evidentiary hearing, the district court granted the preliminary injunction.

The court first determined that it had jurisdiction over the suit. The court explained that petitioners were challenging the "method by which [the] Method [II] reimbursement level was determined" and that such "method" challenges are directly cognizable in federal court under this Court's decision in *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667 (1986). Pet. App. 47a. Next, applying the traditional standards for preliminary relief, the court concluded that petitioners were likely to succeed on the merits (*id.* at 48a-53a);[2] that, absent an injunction, the petitioner patients were likely to suffer irreparable injury because HIC could not afford to continue providing the services under

[2] The court found that petitioners were likely to prevail on four claims: (1) that they had a statutory right to have Method II payments calculated independently of the Method I option; (2) that Blue Cross had no authority to deem HIC's rate for Method II services not "inherently reasonable," because HHS had not provided notice and an opportunity for comment prior to conferring the power to make "inherent reasonableness" determinations on the local carriers (*see* 42 U.S.C. § 1395u(b)(8)(A)); (3) that Blue Cross's decision to set the Method II rate at the Method I level was not based on actual expenses and, therefore, was arbitrary and capricious; and (4) that Transmittal 1237 was invalid because it had regulatory force and therefore could not be adopted without notice and an opportunity for comment.

the new low rate, and reasonable options were not readily available (*id.* at 53a-54a); and that there were no countervailing considerations sufficient to justify denying the injunction (*id.* at 54a-55a).[3]

Respondents appealed the preliminary injunction, challenging the district court's rulings on jurisdiction and on the merits of petitioners' claims. The appeal was mooted, however, when Congress amended the Medicare statute to provide that, effective February 1, 1990, the Method II reimbursement rate for home dialysis could no longer exceed the Method I rate for clinic dialysis. Omnibus Budget Reconciliation Act, Pub. L. No. 101-239, § 6203(b)(1), 103 Stat. 2106 (1989), amending 42 U.S.C. § 1395rr(b)(7). The D.C. Circuit vacated the preliminary injunction and remanded the case to the district court for resolution of the government's contention that HIC should be required to "bear the cost of payments made in excess of the Method I rates while the injunction was in effect." Pet. App. 40a (citing *University of Texas v. Camenisch*, 451 U.S. 390 (1981)).[4]

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[3] The district court initially required a nominal injunction bond of $1000 under Fed. R. Civ. P. 65(c), stating that, even if it subsequently turned out that the preliminary injunction was improvidently granted, "I don't see how anybody in good conscience is going to go and make th[at] a retroactive ruling . . . . That [would] mean[] you would have to go back to all of these people that have been given this care and get the money from them." Tr. of Status Call, Feb. 14, 1989, at 5; *see also* Pet. App. 58a. The government appealed this ruling, and the court of appeals "remanded the record" with instructions to the district court to enter a bond based on "the magnitude of the injury [to respondents] and the risk that the preliminary injunction might be vacated." Order, Jan. 8, 1990. The district court, after an evidentiary hearing, reset the bond at $750,000. Order, Feb. 2, 1990.

[4] On October 23, 1990, after the case was returned to the district court, the parties stipulated to a voluntary dismissal of Blue Cross because the monetary issues that remained to be litigated involved only the federal defendants. Blue Cross is thus not a respondent in this Court.

3. *Proceedings on the Government's Claim for Refund.* On remand, the district court ruled that the government was not entitled to any payments from HIC. The court first reaffirmed its earlier decision finding jurisdiction. Pet. App. 28a. It then concluded that the rates paid under the preliminary injunction were proper because, for the period prior to the new legislation, HIC's legal position was meritorious. *Id.* at 28a-29a. The court found this conclusion bolstered by the recent amendment, because Congress had expressly made the new limit on reimbursement prospective only and had even delayed its effective date to provide "for a transition period" that would enable patients to obtain other means of treatment. *Id.* at 29a. In any event, the court concluded, even if the preliminary injunction had been erroneous, the equities would still defeat the government's claim for recovery. *Id.* at 29a-35a. The court noted, among other considerations, that HIC had delivered the services and incurred expenses in specific reliance on the payment level set by the injunction and thus "awarding the government damages would leave HIC worse off than it would have been had the injunction been denied." *Id.* at 31a.

The court of appeals reversed on the ground that, absent administrative exhaustion, the district court lacked jurisdiction and the preliminary injunction was therefore "invalid." *Id.* at 6a. The court agreed that petitioners' claims were judicially cognizable under the decision in *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667 (1986), but concluded that Congress had overturned that decision *sub silentio* in a 1986 amendment to 42 U.S.C. § 1395ff(b)(1)(C)—even though that amendment dealt only with so-called "amount" challenges, which the *Michigan Academy* Court had expressly differentiated from "method" challenges like the one at issue here. The D.C. Circuit recognized that the other five circuits to have addressed the issue continue to

adhere to the jurisdictional rule of *Michigan Academy*, but it declined to follow this uniform body of precedent, noting that none of these other courts had specifically considered the 1986 amendment. Pet. App. 15a.

This jurisdictional ruling, in turn, led the D.C. Circuit to conclude that it had no power to "address the merits of HIC's claim." Pet. App. 6a. And with that factor eliminated from the equitable balance, the court found that the other considerations relied on by the district court were insufficient to defeat the government's claims for damages and restitution. The court then remanded the case to the district court to decide, in the first instance, the appropriate method for calculating the damages to be recovered under HIC's $750,000 injunction bond. In addition, the court held that the government could pursue a claim for restitution against HIC in an administrative recoupment proceeding.[5]

REASONS FOR GRANTING THE PETITION

This case presents a fundamental question of federal court jurisdiction over challenges to generally applicable rules and regulations governing the availability of bene-

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[5] Without expressly saying so, the court implied that HIC could raise its underlying merits claims—*i.e.*, the ones that led to this litigation—in the recoupment proceeding. The court did state that, "[w]hen those [administrative] procedures have run their full course, HIC may, if not content with the outcome, seek judicial relief in an appropriate forum." Pet. App. 22a.

The court of appeals also did not say whether HIC could pursue administrative, followed by judicial, remedies to get back any monies that it might be required to pay under the bond, based on its contention that the rate set in the preliminary injunction was proper because respondents' effort to lower the Method II rate was unlawful (as the district court had held). The logic of the court of appeals' analysis certainly would allow HIC to seek this relief, given that the merits of its claims have not been resolved and that the government cannot have been ultimately "damaged" if HIC's claims on the merits are right. Based on its position below, we do not understand the government to disagree that HIC can recoup these "damages" if it is right on the merits.

fits under the Medicare program. The court of appeals held that Congress intended each individual affected by such a provision to exhaust a lengthy, multi-tiered administrative process—which is largely and, for some issues, completely powerless to afford relief—before bringing these systemic challenges to court. The D.C. Circuit rested this conclusion on a 1986 amendment to 42 U.S.C. § 1395ff(b)(1)(C), which extended the part A administrative/judicial review procedures of that provision to part B claims as well. The court of appeals flatly misconstrued this amendment.

This Court has already made clear that section 1395ff(b)(1)(C)—which governs disputes concerning the "amount" of benefits—does *not* apply to disputes, like the one at issue here, involving "the *method* by which such amounts are to be determined." *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667, 675 (1986). That authoritative statutory construction was not disturbed when Congress added part B claims to this provision. The clear—and only—purpose of that amendment was to provide a formal administrative/judicial review process for part B "*amount*" claims, which had previously been reviewable exclusively by the local insurance carriers. *See United States v. Erika, Inc.*, 456 U.S. 201 (1982). There is absolutely no basis for the suggestion that Congress was simultaneously overturning *Michigan Academy* so as to cut back procedural rights in "method" cases.

This erroneous jurisdictional ruling warrants immediate review. There is a square conflict in the circuits over the question whether section 1395ff(b)(1)(C) applies to "method" challenges (or only to "amount" challenges). *See* Pet. App. 15a (citing cases). Contrary to the D.C. Circuit's suggestion, moreover, this conflict will not disappear once the other circuits "address[] . . . the 1986 amendment." *Id.* at 15a. Indeed, two of the cases cited by the D.C. Circuit as conflicting with its

decision involved *part A* claims, which cannot possibly be affected by the amendment, because it was limited to *part B* claims. The real reason for this conflict—and for its inevitable persistence—is the D.C. Circuit's disagreement with the other circuits concerning the relationship between *Michigan Academy*'s interpretation of section 1395ff(b)(1)(C) and this Court's earlier, part A decision in *Heckler v. Ringer*, 466 U.S. 602 (1984). That conflict is uniquely this Court's to resolve.

I. THE D.C. CIRCUIT'S DECISION CONTRAVENES THIS COURT'S DEFINITIVE INTERPRETATION OF SECTION 1395ff(b)(1)(C), WHICH WAS NOT OVERTURNED BY THE SUBSEQUENT AMENDMENT TO THAT PROVISION.

Petitioners' claims, precisely like those at issue in *Michigan Academy*, challenge "the validity of [HHS's] instructions and regulations [for determining benefits]" (476 U.S. at 680) and thus, as the D.C. Circuit correctly acknowledged, "fall squarely on the methodology side of the [amount/method] line" recognized in *Michigan Academy*. Pet. App. 12a. The court nevertheless concluded that Congress intended to route such claims through a five-step administrative process before they can come to court—(1) review by the private insurance carrier and (2) a hearing before the carrier (42 U.S.C. § 1395u(b)(3)(C); 42 C.F.R. § 405.801, *et seq.*), followed by (3) review by HCFA, (4) a second hearing before an administrative law judge, and (5) an appeal to the HHS Appeals Council (42 U.S.C. § 1395ff(b); 42 C.F.R. § 405.701, *et seq.*). *See Isaacs v. Bowen*, 865 F.2d 468 (2d Cir. 1989).

That is a surprising conclusion, if only because one would not normally expect such a time-consuming, cumbersome administrative process to apply to the kind of legal issues raised by a "method" challenge—*i.e.*, whether a regulation or instruction violates the Constitution, the Medicare statute, or the Administrative Procedure Act,

5 U.S.C. § 500, *et seq.* Indeed, the review and hearing before the carrier, though mandatory, are indisputably futile since the legality of HHS's regulations and instructions cannot be considered at that level. *See* 42 C.F.R. § 405.860; *Michigan Academy*, 476 U.S. at 675-76. And even at higher levels of the process, a challenge to a HCFA regulation (but apparently not to an instruction) is also futile. *See* 42 C.F.R. § 408.108(c).

The reasoning that led the D.C. Circuit to conclude that Congress intended to adopt this kind of administrative review scheme for generic legal claims is as flawed as the result is surprising. In particular, two basic errors infect the court's analysis. First, it misread the trilogy of this Court's cases interpreting the Medicare statute's provisions concerning judicial review—*Erika* (1982); *Ringer* (1984); and *Michigan Academy* (1986). And second, it misinterpreted Congress's post-*Michigan Academy* amendments changing the Medicare appeals process.

1.a. The contours of federal court jurisdiction over Medicare claims initially were developed independently for part A and part B claims. As to the former, the Medicare statute has always provided (subject to jurisdictional amounts not at issue here):

> Any individual dissatisfied with any determination [of] . . . the amount of benefits under part A (including a determination where such amount is determined to be zero) . . . shall be entitled to a hearing thereon by the Secretary to the same extent as is provided in section 405(b) of this title and to judicial review of the Secretary's final decision after such hearing as is provided in section 405(g) of this title.

42 U.S.C. § 1395ff(b)(1)(C).[6] With respect to part B claims, on the other hand, until 1986 the statute provided

[6] Sections 405(b) and 405(g), which are incorporated into this provision, set forth, respectively, the administrative hearing requirements and the judicial review requirements for claimants under the Social Security Act, 42 U.S.C. § 300, *et seq.*

only for "a fair hearing, by the [insurance] carrier, in any case where the amount in controversy is at least $100." 42 U.S.C. § 1395u(b)(3)(C).

In 1982, in *Erika*, this Court considered a part B challenge to an insurance carrier's determination of the amount to be paid for certain medical equipment. The Court held that Congress intended to limit review of such determinations to a hearing before the carrier. The Court based this decision on the marked difference between the review provision for part A, section 1395ff(b)(1)(C), and the then-existing review provision for part B, section 1395u(b)(3)(C). This conclusion was reinforced by the legislative history indicating that these different review procedures were warranted because "payments under the Part B program generally were expected to be smaller than those under the primary Part A program." 456 U.S. at 208.

Two years later, in *Ringer*, the Court required administrative exhaustion prior to a judicial challenge by part A claimants seeking coverage for a specific surgical procedure that HHS had refused to allow. Employing a different analysis with respect to the two types of claimants involved in the case—those who had already received the treatment and wanted reimbursement, and those who had not had the surgery for fear that they would not be reimbursed—the Court ultimately concluded that neither group could proceed directly to court. As to the first group, the Court rejected the lower court's conclusion that "procedural" challenges, unlike "substantive" challenges, could be brought without exhaustion. The Court reasoned that exhaustion was required because, "at bottom," these individuals were claiming that "they should be paid for their . . . surgery" (466 U.S. at 614). The Court likewise concluded that the one individual who had not yet had the surgery was nevertheless "essentially . . . requesting the payment of benefits" (*id.* at 620), and although he had no immediate claim to exhaust, that fact meant only that his challenge was premature, not that

the federal courts had jurisdiction to issue "advisory opinions" (*id.* at 622).

The final case in the trilogy, *Michigan Academy*, while specifically involving a part B claim, ended up bridging the review processes for both parts. A group of family physicians sought direct judicial review of an HHS regulation setting their fees at a level lower than that applicable to specialists. Distinguishing *Erika*, the Court unanimously held that such a claim was not barred by the Medicare statute and thus could be brought pursuant to 28 U.S.C. § 1331. The Court reasoned that, by their terms, both the part B review provision at issue in *Erika* (§ 1395u(b)(3)(C)) and the part A provision at issue in *Ringer* (§ 1395ff(b)(1)(C)) apply only to challenges disputing the "amount" of benefits received by a recipient, whereas the claim at issue in *Michigan Academy* challenged HHS's "method" of determining benefits. The Court explained:

> The reticulated statutory scheme, which carefully details the forum and limits of review of "any determination . . . of . . . the amount of benefits under part A," 42 U.S.C. § 1395ff(b)(1)(C) (1982 ed., Supp. II), and of the "amount of . . . payment" of benefits under part B, 42 U.S.C. § 1395u(b)(3)(C), simply does not speak to challenges mounted against the *method* by which such amounts are to be determined rather than the *determinations* themselves.

476 U.S. at 675.

In sum, after *Michigan Academy*, this Court's cases made clear that judicial review of Medicare claims was governed by the following principles: (1) section 1395ff(b)(1)(C) applied to "amount" challenges to part A payments; (2) section 1395u(b)(3)(C) applied to "amount" challenges to part B payments; and (3) the Medicare statute being silent as to "method" challenges under both parts, such challenges were directly cognizable in federal court under 28 U.S.C. § 1331.

b. The court of appeals in this case nevertheless concluded that, even after *Michigan Academy*, "method" challenges under *part A* were not directly cognizable under 28 U.S.C. § 1331, but could be brought only pursuant to section 1395ff(b)(1)(C), with its exhaustion requirement. The court reached this result by insisting that *Ringer* was a part A "method" case and that nothing in *Michigan Academy* purported to affect *Ringer*. Pet. App. 12a-13a. This reading of the cases, however, is not supportable.

To start with the obvious, the amount/method distinction was never raised or discussed in *Ringer*. Moreover, as just noted, *Michigan Academy* explicitly construed—and rested its holding on—the "amount" language of *both* the part A provision (§ 1395ff(b)(1)(C)) and the part B provision (§ 1395u(b)(3)(C)), recognizing the textual part A/part B parallelism in "the reticulated statutory scheme" (476 U.S. at 675). This textual analysis simply cannot be squared with the D.C. Circuit's position that part A "method" claims require exhaustion.[7] Consequently, even if *Ringer*, standing alone, could be read to support a broad exhaustion rule, that would only mean that "*Michigan Academy* . . . severely restricted the decision in *Ringer*." *Medical Fund-Philadelphia Geriatric*

[7] The court below never mentioned the textual basis for the decision in *Michigan Academy*. Instead, it pointed out that there was no statutory provision for part B appeals beyond the carrier level prior to 1986 and then portrayed *Michigan Academy* as resting essentially on "the 'strong presumption that Congress intends judicial review of administrative action.'" Pet. App. 11a (quoting 476 U.S. at 670). Although this Court's decision relied on that presumption, the fact remains that the Court construed the provision on "amount" claims not to include "method" claims. That construction was essential to the holding because, as the *Michigan Academy* Court explained, "[t]he presumption of judicial review is, after all, a presumption," to which "Congress can, of course, make exceptions." 476 U.S. at 672-73. Indeed, in *Erika*, the Court had already ruled that Congress intended to bar judicial review for a broad category of part B claims. *Michigan Academy*'s construction of the statutory term "amount" established that Congress had not made any exception to the presumption for "method" challenges.

Center v. Heckler, 804 F.2d 33, 38 (3d Cir. 1986). Indeed, the *Michigan Academy* Court specifically characterized the claims of the individuals in *Ringer* who had received treatment and were seeking reimbursement as involving a challenge only to "*amount* determinations." 476 U.S. at 677 n.7 (emphasis added).

In accord with these principles, the other courts of appeals to have addressed the issue have recognized that part A "method" claims are immediately cognizable in court under *Michigan Academy*. The First Circuit in *McCuin v. Secretary of Health and Human Servs.*, 817 F.2d 161 (1987), flatly held that "*Michigan Academy's* analysis of challenges to Part B provisions is applicable to the present [procedural] challenge to Part A regulations." *Id.* at 165. And the Seventh Circuit, in *dicta*, likewise has stated that the *Michigan Academy* distinction between "amount" and "method" claims applies to part A and part B alike. *Bodimetric Health Servs., Inc. v. Aetna Life & Cas.*, 903 F.2d 480, 484-87 (7th Cir.), *cert. denied*, 111 S. Ct. 579 (1990).

2. The D.C. Circuit compounded its error by misreading the 1986 amendments to section 1395ff(b). Those amendments, far from undoing the decision in *Michigan Academy*, as the court of appeals here held, actually ratify that holding.

The 1986 amendment to section 1395ff(b)(1)(C) added the words "or part B," so that the provision now reads: "Any individual dissatisfied with any determination . . . [of] the amount of benefits under part A *or part B* of this subchapter" shall exhaust administrative remedies before seeking judicial review. The court below, having found that part A "method" claims (just like "amount" claims) had to be exhausted (*see* p. 14, *supra*), read this amendment to mean that Congress intended to overturn *Michigan Academy* by extending the part A provision to part B claims. This reading of the amendment is facially flawed because, as we just explained, it is built

on the false premise that, prior to the amendment, the section applied to part A "method" claims. More fundamentally, the D.C. Circuit's reading is wrong because it entirely disregards the language and legislative history of both the amendment itself and an accompanying amendment to section 1395ff(b).

As a textual matter, the D.C. Circuit's analysis ignores the operative word "amount," which provided the statutory basis for the decision in *Michigan Academy*. Thus, had Congress wanted to undo the decision, it surely would have specifically addressed this dispositive word—by changing the text of section 1395ff(b)(1)(C) to provide, for example, that the section applies to "[a]ny individual dissatisfied with the amount of, *or the method used in determining*, benefits . . . ." But Congress made no such change when it amended this section shortly after the decision in *Michigan Academy*.

The legislative history further confirms that Congress did not intend to undo *Michigan Academy*. To start with, of course, if Congress had meant to overturn a prominent decision of this Court and deprive litigants of previously available judicial review rights, its explanation of the amendment would almost certainly have said as much. Yet, neither of the relevant committee reports contains anything remotely suggesting that Congress intended such a result. *See* H.R. Rep. No. 727, 99th Cong., 2d Sess. 95 (1986), reprinted in 1986 U.S.C.C.A.N. 3607, 3685; H.R. Conf. Rep. No. 1012, 99th Cong., 2d Sess. 351 (1986), reprinted in 1986 U.S.C.C.A.N. 3868, 3996. On the contrary, those reports and the other legislative materials demonstrate that the 1986 amendment, which was actually drafted more than a year *before* this Court decided *Michigan Academy*, was enacted to provide new review rights for part B "amount" claims—that is, to overturn the holding in *Erika* that amount determinations under part B could be challenged only through an informal hearing before an insurance carrier, with no oppor-

tunity for further administrative or judicial review.[8] Reviewing this legislative history, even the D.C. Circuit was constrained to acknowledge that "[it] does show a focus on what Congress was affirmatively doing—opening up part B 'amounts' determinations to judicial review on the same basis as disputes under part A." Pet. App. 14a.

Nor is there any basis for the suggestion—made by the government and apparently accepted by the court below (*id.* at 11a)—that the amendment was passed because Congress "recognized" that *Michigan Academy*'s allowance of direct "method" challenges had created a "problem," to which Congress "reacted swiftly." U.S. Br. at 21. That view is disproved by the fact that the amendment had been drafted, and hearings held on it, long before the decision in *Michigan Academy*; and no change was made in its language after the decision came down. *See* note 9, *infra*. In short, the amendment was aimed solely at expanding rights in response to *Erika*, not at limiting rights in response to *Michigan Academy*.

The absence of any intent to overturn *Michigan Academy*'s construction of the "amount" language is also demonstrated by Congress's simultaneous adoption of an additional amendment to section 1395ff(b)—*this one* drafted after, and in specific response to, *Michigan Academy*.[9] Thus, in Pub. L. No. 99-509, § 9341(a)(1)(D),

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[8] In addition to the House and Conference Reports cited in text, *see also* Hearings on S. 1158 Before the Subcommittee on Health of the Senate Committee on Finance, 99th Cong., 1st Sess. (1985); 131 Cong. Rec. 29833 (1985) (statement of Rep. Wyden, House sponsor); 131 Cong. Rec. 22267 (1985) (statement of Sen. Durenberger, Senate sponsor).

[9] The language amending section 1395ff(b)(1)(C) to include part B was originally proposed in two bills introduced in 1985. H.R. 2684; S. 1551. That language was passed by the House, without relevant change, as part of the proposed Omnibus Budget Reconciliation Act, shortly after *Michigan Academy*, on September 24, 1986. 132 Cong. Rec. 25941. In conference, the Senate accepted the House version, again without any change of the pre-*Michigan*

100 Stat. 2038 (1986) (codified at 42 U.S.C. § 1395ff (b)(4)), Congress provided that "[a] regulation or instruction which relates to a *method* for determining the amount of payment under part B [of this subchapter] and which was initially issued before January 1, 1981, shall not be subject to judicial review" (emphasis added). In this section, Congress *did* limit *Michigan Academy*'s direct judicial-access rule, but only as applied to challenges to *pre*-1981 regulations and instructions—which were, in effect, immunized from judicial review under a grandfather provision. This amendment thus explicitly embodies Congress's adoption, not repudiation, of *Michigan Academy*'s amount/method distinction. And it implicitly, though unmistakably, establishes that method challenges to rules adopted *after* 1981 (like the one at issue here) continue to be subject to direct court challenge, as provided for in *Michigan Academy*. This necessary implication was specifically recognized by the principal sponsor of the amendment to section 1395ff(b)(1)(C), who stated on the date of its passage: "[t]his legislation *strengthens* the rights established by the Supreme Court in its decision, Bowen versus Michigan Academy of Family Physicians, earlier this year." 132 Cong. Rec. 32978 (1986) (statement of Rep. Wyden) (emphasis added).

In summary, the text of the 1986 amendments to section 1395ff(b) and their legislative history provide no support for—indeed, they powerfully undermine—the D.C. Circuit's remarkable conclusion that Congress intended to overturn the decision in *Michigan Academy* without ever saying so.

Academy language regarding section 1395ff(b)(1)(C). H.R. Conf. Rep. No. 1012, at 350, reprinted in 1986 U.S.C.C.A.N. at 3995. At the same time, the conferees added the *new* provision discussed in text. H.R. Conf. Rep. No. 1012, at 351, reprinted in 1986 U.S.C.C.A.N. at 3996. The bill as it came out of conference was passed by the Congress on October 17, 1986. 132 Cong. Rec. 32979, 33313 (1986).

II. THE INTERCIRCUIT CONFLICT REGARDING THE SCOPE OF SECTION 1395ff(b)(1)(C) SHOULD BE RESOLVED NOW.

The D.C. Circuit acknowledged that its interpretation of section 1395ff(b)(1)(C)—as applying to "method" as well as "amount" claims—conflicts with the interpretation of that provision followed in the other circuits. *See* Pet. App. 15a (citing *Bodimetric Health Servs., Inc. v. Aetna Life & Casualty*, 903 F.2d 480 (7th Cir. 1990); *Texas Medical Ass'n v. Sullivan*, 875 F.2d 1160 (5th Cir.), *cert. denied*, 493 U.S. 1011 (1989); *Isaacs v. Bowen*, 865 F.2d 468, 471 (2d Cir. 1989); *Association of Seat Lift Manufacturers v. Bowen*, 858 F.2d 308, 316-17 (6th Cir. 1988), *cert. denied*, 489 U.S. 1078 (1989); *Kuritzky v. Blue Shield*, 850 F.2d 126, 128 (2d Cir. 1988), *cert. denied*, 488 U.S. 1006 (1989); *McCuin v. Secretary of Health & Human Servs.*, 817 F.2d 161, 164-66 (1st Cir. 1987)). But the court brushed aside this conflict on the ground that "*not one* of these cases addresses or even mentions the 1986 amendment." Pet. App. 15a.

That observation provides no reason to defer consideration of this important jurisdictional issue. In the first place, if the court meant to suggest that, once the amendment was considered by the other circuits, this conflict would disappear, its suggestion rests on a fundamental misunderstanding of the basis for the conflict. Moreover, even if there were any likelihood that the conflict might someday evaporate, the cost of waiting, while this jurisdictional issue is repeatedly litigated on a case-by-case basis, makes that alternative unacceptable.

1. The conflict over the scope of section 1395ff(b)(1)(C) is unaffected by the 1986 amendment to that provision. The statutory question presented turns entirely on whether the *Michigan Academy* amount/method distinction applies to the "amount" language of section 1395ff(b)(1)(C)—which, before 1986, governed only part

A claims. That question in turn depends solely on whether *Michigan Academy*'s express language so construing section 1395ff(b)(1)(C) is to be followed, or instead is to be ignored based on a reading of *Ringer* as having construed section 1395ff(b)(1)(C) otherwise. The dispute, then, is simply over the proper reading of two cases interpreting the scope of this statutory provision *prior to the 1986 amendments*. Thus, even the D.C. Circuit would seem to agree that if *Michigan Academy*'s express interpretation of section 1395ff(b)(1)(C) meant what it says —so that part A "method" claims have always been outside the provision's scope—then the same must be true of part B claims. *See* Pet. App. 12a ("[t]here is, indeed, no difference in the statutory provision governing judicial review of parts A and B"). The 1986 amendment to section 1395ff(b)(1)(C) has no bearing on resolution of the conflict over how to read *Ringer* and *Michigan Academy*.

That the source of the conflict is the D.C. Circuit's conclusion that *Ringer* and *Michigan Academy* are at odds—and not any statutory change wrought by the 1986 amendment—is demonstrated by the fact that two of the cases cited by the D.C. Circuit as being in conflict with its decision applied the amount/method distinction in *part A* cases. *See McCuin; Bodimetric Health Services*. Those decisions could not possibly have been affected by the 1986 amendment to section 1395ff(b)(1)(C), because the amendment concerned *only* part B. Similarly, the courts of appeals that continue to apply the amount/method distinction in part B cases also recognize that *Michigan Academy* definitively construed section 1395ff(b)(1)(C) to exclude part A "method" cases. *Texas Medical Ass'n*, 875 F.2d at 1165; *Kuritzky*, 850 F.2d at 128; *Medical Fund-Philadelphia Geriatric Center*, 804 F.2d at 38. These circuits cannot be expected, therefore, to change their rulings when the 1986 amendment is highlighted to them. Indeed, the large majority of district courts addressing

the 1986 amendment have already concluded, on the basis of the analysis presented here, that the amendment leaves the *Michigan Academy* rule on *part B* "method" claims intact.[10]

2. In addition to the almost certain futility of waiting to see if this conflict disappears, there is another reason that compels review now: delay will result in an enormous waste of judicial resources, as events already demonstrate. There is simply no realistic way of avoiding repeated adjudications of this jurisdictional issue: "method" challenges are frequent, and plaintiffs typically can choose what circuit to bring them in, since they involve nationally applicable rules. The resulting proliferation of rulings, in turn, creates the prospect of many potential advisory opinions on the merits of Medicare challenges, as many district courts predictably conclude, following their circuit-court precedent and the analysis set forth here, that jurisdiction is available.

This prospect is far from hypothetical. As we just pointed out, several district courts have already held that the 1986 amendment does not bar jurisdiction over "method" claims (*see* note 10, *supra*); and those courts have then gone on to address the underlying merits of

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[10] *See Pulmocare Pharmacy, Inc. v. Sullivan*, 1992 Medicare and Medicaid Guide (CCH) ¶ 40,387 (D. Or. 1992); *Blue Bell Medical, Inc. v. Pennsylvania Blue Shield*, 775 F. Supp. 829, 831-33 (M.D. Pa. 1991); *Outpatient Ophthalmic Surgery Society, Inc. v. Sullivan*, 1990 Medicare and Medicaid Guide (CCH) ¶ 38,981 (D.D.C. 1990); *Vorster v. Bowen*, 709 F. Supp. 934, 939-40 (C.D. Cal. 1989); *Griffith v. Bowen*, 678 F. Supp. 942, 945 (D. Mass. 1988); *Health Indus. Distribs. Ass'n v. Bowen*, 1987 Medicare and Medicaid Guide (CCH) ¶ 36,748 (D.D.C. 1987). Only two district courts have sided with the government. *Roen v. Sullivan*, 764 F. Supp. 555, 561 (D. Minn. 1991); *Colorado Clinical Labs, Inc. v. Newman*, 1990 Medicare and Medicaid Guide (CCH) ¶ 39,056 (N.D. Tex. 1990). *Cf. also Oxygen Equip. Co. v. Sullivan*, 1989 Medicare and Medicaid Guide (CCH) ¶ 37,989 (N.D. Ala. 1989), *aff'd without opinion*, 914 F.2d 268 (11th Cir. 1990).

the regulatory challenges. Indeed, at least one district court, based on an analysis similar to ours, has already specifically rejected the D.C. Circuit's decision in this case. *Pulmocare Pharmacy, Inc. v. Sullivan*, 1992 Medicare and Medicaid Guide (CCH) ¶ 40,387, at 31,600 (D. Or. 1992) ("[a]lthough *National Kidney Patients* adopted the very argument defendants here propose, I decline to follow that decision"). There is no reason to tolerate such an inefficient process for resolving a jurisdictional issue of national significance.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

JOEL I. KLEIN *
PAUL M. SMITH
RICHARD G. TARANTO
KLEIN, FARR, SMITH & TARANTO
2550 M Street, N.W.
Washington, D.C. 20037
(202) 775-0184
* *Counsel of Record*

APPENDICES

TABLE OF CONTENTS

APPENDIX A

Page

Decision of the United States Court of Appeals for the District of Columbia Circuit, Mar. 13, 1992 .... 1a

APPENDIX B

Decision of the United States District Court for the District of Columbia, Jan. 17, 1991 ..... 23a

APPENDIX C

Decision of the United States Court of Appeals for the District of Columbia Circuit, Apr. 24, 1990 .... 36a

APPENDIX D

Transcript of Proceedings before the United States District Court for the District of Columbia, Dec. 22, 1988 ..... 43a

APPENDIX E

Order of the United States Court of Appeals for the District of Columbia Circuit, Denying Rehearing, June 1, 1992 ..... 59a

APPENDIX A

UNITED STATES COURT OF APPEALS
DISTRICT OF COLUMBIA CIRCUIT

No. 91-5073

NATIONAL KIDNEY PATIENTS ASSOCIATION, *et al.*

v.

LOUIS W. SULLIVAN, M.D., Secretary,
Department of Health and Human Services, *et al.*,
Appellants.

On Appeal from the United States District Court
for the District of Columbia Circuit
(Civil Action No. 88-03251)

Argued Nov. 15, 1991

Decided March 13, 1992

Rehearing and Rehearing En Banc
Denied June 1, 1992

Before: RUTH BADER GINSBURG, WILLIAMS and SENTELLE, Circuit Judges.

Opinion for the Court filed by Circuit Judge STEPHEN F. WILLIAMS.

STEPHEN F. WILLIAMS, Circuit Judge:

For slightly over 13 months the Department of Health and Human Services made payments to Home Intensive Care, Inc. ("HIC") under a preliminary injunction issued by the district court. As a result of congressional action, that injunction has been modified and the modified injunction has been vacated as moot. While it was in effect, however, HHS paid HIC millions of dollars—HHS says $15 million—more than it otherwise would have. Here it asks that we reverse the district court's decision preventing it from recouping those sums, and instead allow it both to recover on a $750,000 injunction bond and to apply its usual administrative recoupment processes to the transactions with HIC. We agree, and reverse the order of the district court.

Background

Part B of Medicare provides supplementary medical insurance for the aged and disabled, generally covering 80% of the "reasonable charge" for physicians' services, durable medical equipment, out-patient hospital services, lab services, and so on. HHS enters into contracts with private insurance carriers—in this case with Blue Cross and Blue Shield of Florida ("Blue Cross")—who handle the routine administration of part B. Carriers like Blue Cross establish "reasonable" charges that providers can recover under Medicare.

In 1972 Congress extended part B coverage to individuals who have permanent kidney failure (regardless of age), and who therefore require transplantation or dialysis. 42 U.S.C. § 1395rr. In doing so, it established two alternative methods of payment, commonly known as "Method I" and "Method II." Method I provides for reimbursement by HHS to a *certified* facility for dialysis treatment administered by the facility. 42 U.S.C. §§ 1395 ff(b)(1)(A), 1395rr(b)(7). Method II—now obsolete—

provided for reimbursement by HHS to or on behalf of individuals for the costs of home dialysis supplies and equipment *supplied by an entity other than a certified facility.* 42 U.S.C. § 1395rr(b)(1)(B). Although both methods encompassed home dialysis, Method II enabled patients who self-dialysized at home to contract directly for equipment and supplies rather than receiving them from a certified facility. Method II coverage was limited to a "reasonable charge". 42 U.S.C. § 1395u(b)(3).

"Reasonable charge" determinations for some time proceeded largely under two criteria—the supplier's customary charges and rates prevailing in the locality. See 42 CFR § 405.502(a)(1) & (2). In February 1986 HHS proposed to amplify § 405.502 with a new subsection, (g), to catch instances where those criteria would result in "unreasonably excessive charges." See Notice of Proposed Rule, Medicare Program; Reasonable Charge Limitations, 51 Fed.Reg. 5726, 5728 (1986). Before HHS made the regulation final, Congress adopted a similar provision, 42 U.S.C. § 1395u(b)(8), requiring HHS to describe by regulation instances where standard criteria would lead to a charge that was so "grossly excessive" (or "grossly deficient") as not to be "inherently reasonable". Pub.L. No. 99-272 § 9304(a), now codified at 42 U.S.C. § 1395u(b)(8)(A). The new statutory subsection also required HHS to state the factors to be considered in establishing "reasonable" charges. *Id.*

After the statutory amendment, HHS adopted its proposed 42 CFR § 405.502(g), setting forth a non-exhaustive list of factors that might trigger scrutiny for inherent unreasonableness, and stating criteria for setting reasonable charges when the existing charge was found grossly excessive. As adopted, subsection (g) not only authorized the Health Care Financing Administration ("HCFA") to use these factors to establish charge limits, but gave similar authority at the local level to carriers

such as Blue Cross. Final Rule, Medicare Program; Reasonable Charge Limitations, 51 Fed.Reg. 28710 (1986). In its district court suit, HIC claimed that the extension of authority to carriers was unlawful for want of notice and comment on that issue.

In February 1988 HCFA issued a letter to carriers, Transmittal Letter 1237 ("TL 1237"), on the subject of home dialysis. It advised them to consider the application of the inherent unreasonableness criteria to Method II reimbursement for home dialysis. It asserted that "[v]arious data" suggested that Method II providers were paid primarily by Medicare, that they did not engage in price competition, that their charges often greatly exceeded their costs, and that in significant respects they provided fewer items than were provided for less money under Method I. See Joint Appendix ("J.A.") 51-52. Although TL 1237 did not bar Method II charges in excess of Method I levels, it certainly suggested that any such excesses were quite likely to be "inherently unreasonable".

In July 1988 Blue Cross started to exercise its authority under § 405.502(g), issuing a notice that proposed to reduce the maximum monthly allowance for home dialysis supplies and equipment under Method II from $3,100 to $1,625 (the Method I reasonable amount), and calling for more data. In October 1988, after surveying the data, Blue Cross adopted the proposed ceiling, effective January 1, 1989.

Soon after Blue Cross's announcement, plaintiffs—HIC (which supplies dialysis under Method II to about 1000 Florida patients), a renal dialysis patients' group, and 10 individual renal dialysis patients receiving equipment from HIC—proceeded directly to district court, seeking a preliminary injunction barring HHS, HCFA, and Blue Cross from implementing the new rate reduction. Plaintiffs

(usually referred to here simply as HIC) complained that (1) HHS's grant of "inherent unreasonableness" authority to carriers as well as to HCFA should have been preceded by notice and comment; (2) TL 1237 was a substantive rule requiring notice and comment; and (3) any capping of the Method II reimbursement at Method I levels was arbitrary and capricious. In December 1988 the district court issued the requested injunction. Though initially setting no injunction bond at all, the court in February 1989 required a nominal one—$1,000.

The federal defendants promptly appealed on a number of grounds, including the size of the bond. In December 1989 we remanded the record to the district court, instructing it to set "an appropriate bond" and stating that Medicare had already paid over $18 million to vendors under the injunction, an amount for which the $1000 bond was "clearly inadequate to ensure repayment". *National Kidney Patients Ass'n v. Sullivan*, Order, No. 89-5039 (D.C.Cir., Dec. 8, 1989).

Shortly after our ruling, Congress commanded what the district court had enjoined. Section 6203(b)(1) of the 1989 Omnibus Budget Reconciliation Act amended 42 U.S.C. § 1395rr(b)(7) to cap Method II payments at the Method I level, effective February 1, 1990. On that date the district court modified its injunction to allow reduction of payments, and on the next day it ordered HIC to post a $750,000 bond. J.A. 90-92. HHS and Blue Cross again appealed, arguing that the injunction had been improvidently granted. This court held that the appeal had been mooted, and vacated the injunction. *National Kidney Patients Ass'n v. Sullivan*, 902 F.2d 51, 55 (D.C.Cir.1990). As to the defendants' claims for recoupment of amounts paid out under the injunction, the court said that those claims were not properly presented on appeal, but must first be determined by the district court. *Id.* at 54.

On remand, the district court held that HHS could recover neither the $750,000 covered by bond nor any other

payments under the injunction. *National Kidney Patients Ass'n v. Bowen*, 754 F.Supp. 900 (D.D.C.1991). The court stated that its initial ruling granting the injunction was correct as to both jurisdiction and the merits, and that in any case it would be inequitable to permit HHS to recover from HIC.

The defendants appeal, arguing that the district court had no jurisdiction, that it was wrong on the merits, and that HHS should be entitled to recovery of the amounts paid under the injunction. The recovery would come in the form of payment on the bond and through application of HHS's standard administrative process for recoupment of excess amounts paid to a Medicare provider.

The District Court's Jurisdiction

Plaintiffs argue that even if the district court were altogether in error as to jurisdiction or the merits, "equitable considerations" would require us to uphold its denial of relief on the bond and in restitution. Appellees' Brief at 17. But for obvious reasons the law draws a vital distinction in this context between a valid and an invalid decree. See, e.g., *Coyne-Delany Co. v. Capital Dev. Bd.*, 717 F.2d 385 (7th Cir.1983). Accordingly, we must consider whether the district court had jurisdiction. As we conclude that it did not, we need not—indeed, cannot—address the merits of HIC's claim.

Resolution of the jurisdictional issue requires a choice between two lines of precedent. On one side is a line of Social Security cases—*Mathews v. Diaz*, 426 U.S. 67, 96 S.Ct. 1883, 48 L.Ed.2d 478 (1976); *Mathews v. Eldridge*, 424 U.S. 319, 96 S.Ct. 893, 47 L.Ed.2d 18 (1976); *Weinberger v. Salfi*, 422 U.S. 749, 95 S.Ct. 2457, 45 L.Ed.2d 522 (1975)—followed by a part A Medicare decision, *Heckler v. Ringer*, 466 U.S. 602, 104 S.Ct. 2013, 80 L.Ed. 2d 622 (1984). These construe §§ 405(g) and 405(h) of the Social Security Act, 42 U.S.C. §§ 405(g) & (h), both as originally enacted and as later incorporated by refer-

ence into Medicare part A, as establishing a rigorous scheme requiring both "presentment" (an absolute prerequisite) and exhaustion (a prerequisite that may be excused only under rather limited conditions). On the other side is a rule that the Supreme Court developed for Medicare part B disputes at a time when the statutes treated them differently from ones under part A. Under this approach, disputes over "amounts" were (per statute) completely removed from judicial review, see *United States v. Erika, Inc.*, 456 U.S. 201, 102 S.Ct. 1650, 72 L.Ed.2d 12 (1982), whereas disputes over "methodology" could be brought under 28 U.S.C. § 1331's provision for general federal question jurisdiction, subject only to conventional exhaustion requirements, see *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667, 106 S.Ct. 2133, 90 L.Ed.2d 623 (1986).

If the *Salfi-Ringer* line controls, then HIC's failure to "present" its claim to the Secretary's delegate, the insurance carrier, bars jurisdiction. If the *Erika-Michigan Academy* line controls, the district court plainly had jurisdiction, as the dispute was over methodology. Because Congress has now brought Medicare part B disputes under the same regime as ones under part A, and because the Supreme Court has treated part A disputes as indistinguishable from Social Security ones, we find the *Salfi-Ringer* line controlling.

First the basic statutory scheme: Two titles of the Social Security Act are pertinent—Title II, which contains the Old Age, Survivors, and Disability Insurance, Supplemental Security Income, and Social Security Disability programs; and Title XVIII, which contains the Medicare program, Parts A and B (the latter being our concern here). Title II includes jurisdictional provisions that Congress for the most part incorporated into Title XVIII. Section 405(g) of Title II, 42 U.S.C. § 405(g), provides

for district court review of claims by persons seeking benefits under any of the Title II programs:

> Any individual, *after* any final decision of the Secretary made after a hearing to which he was a party, . . . may obtain a review of such decision by a civil action. . . . brought in [a] district court of the United States. . . .

42 U.S.C. § 405(g) (emphasis added). Section 405(h), 42 U.S.C. § 405(h), makes § 405(g) the *exclusive* avenue for judicial review of administrative decisions under Title II, displacing federal court jurisdiction under 28 U.S.C. § 1331:

> The findings and decision of the Secretary after a hearing shall be binding upon all individuals who were parties to such hearing. No findings of fact or decision of the Secretary shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the United States, the Secretary, or any officer or employee thereof shall be brought under section 1331 or 1346 of title 28 to recover on any claim arising under this subchapter.

42 U.S.C. § 405(h).

The Medicare title, Title XVIII, incorporates the jurisdictional sections of Title II: Section 1395ff(b) expressly incorporates § 405(g) of Title II. We give the text first in the form it had *before* congressional amendment on October 21, 1986:

> (1) Any individual dissatisfied with any determination under subsection (a) of this section as to— . . .
>
> > (C) the amount of benefits under part A . . . of this subchapter (including a determination where such amount is determined to be zero) . . .
>
> shall be entitled to a hearing thereon by the Secretary to the same extent as is provided in section

> 405(b) of this title and to judicial review of the Secretary's final decision after such hearing as is provided in section 405(g) of this title.

42 U.S.C. § 1395ff(b) (1982). The October 21, 1986 amendment extended review under § 1395ff(b)(1)(C) to claims under *part B* as well as under part A. Pub.L. No. 99-509, § 9341(a)(1)(B). Thus, subsection (C) now reads:

> (C) the amount of benefits under part A *or part B* of this subchapter (including a determination where such amount is determined to be zero)

42 U.S.C. § 1395ff(b)(1)(C) (1988) (emphasis added).

Finally, § 1395ii expressly incorporates § 405(h), with its preclusive effect on other jurisdiction:

> The provisions of sections 406, and 416(j) of this title, and of subsections (a), (d), (e), *(h)*, (i), (j), (k), and *(l)* of section 405 of this title shall also apply with respect to this subchapter to the same extent as they are applicable with respect to subchapter II of this chapter.

42 U.S.C. § 1395ii (1988) (emphasis added).

Among the cases applying these provisions to claims involving Title II, the clearest is *Mathews v. Eldridge*, 424 U.S. 319, 96 S.Ct. 893, 47 L.Ed.2d 18 (1976). There the Court explained that § 405(g)'s provision for review "after any final decision of the Secretary made after a hearing" imposed two requirements, a "nonwaivable" requirement "that a claim for benefits shall have been *presented* to the Secretary", *id.* at 328, 96 S.Ct. at 897 (emphasis added), and a waivable requirement that administrative remedies provided by the Secretary be exhausted, *id.* The presentment requirement—arising out of § 405(g)'s requirement of "some decision by the Secretary", *id.*, "is an essential and distinct pre-condition for § 405(g) jurisdiction", *id.* at 329. It is a "crucial pre-

requisite". *Id.* The "by the Secretary" phrase, however, is not understood literally--if it were, presentment would merge with exhaustion. The Court found presentment in *Eldridge*, for example, on the basis of the claimants' having presented their claims to the local Social Security office and on appeal to the regional office. *Id.* See also *Weinberger v. Salfi*, 422 U.S. 749, 95 S.Ct. 2457, 45 L.Ed.2d 522 (1975).

In *Heckler v. Ringer*, 466 U.S. 602, 104 S.Ct. 2013, 80 L.Ed.2d 622 (1984), the Court extended the *Salfi-Eldridge* line of cases to part A of Medicare, observing that judicial review of Medicare claims "is available only after the Secretary renders a 'final decision' on the claim, *in the same manner* as is provided in 42 U.S.C. § 405(g) for old age and disability claims arising under Title II of the Social Security Act", citing 42 U.S.C. § 1395ff(b)(1)(C). *Id.* at 605 (emphasis added). (At the time that statement was inapplicable as to part B claims, but the remark appears entirely accurate by virtue of the October 1986 amendment.) The decision cites *Eldridge* and *Salfi* throughout, without betraying the slightest doubt that what was true of § 405(h) in its original context was equally true when it was transported to Medicare by § 1395ii. Justice Stevens's opinion, concurring in part and dissenting in part, makes the same assumption. *Ringer*, 466 U.S. at 627-47, 104 S.Ct. at 2028-38.

Ringer is of special interest for our purposes in that one respondent (Ringer himself) lost because he sought a judicial invalidation of the Secretary's policy against reimbursement of a specific class of operation that he contemplated having in the *future*. As "Congress clearly foreclosed the possibility of obtaining such advisory opinions from the Secretary herself", the Court refused to read § 405(h) so as "to undercut that choice by allowing federal judges to issue such advisory opinions." *Id.* at 621-22, 104 S.Ct. at 2025. Though the exact meaning of

"presentment" may be unclear, the requirement seems well suited to preventing a provider from securing an advance decision such as HIC obtained here. Indeed, HIC conceded at oral argument that it had not presented its claim, a concession that is almost certainly sound, as it sued before providing the services covered by the injunction.

In two cases decided before the October 1986 amendment, the Supreme Court interpreted the statute's application to Medicare part B. In the first, *United States v. Erika, Inc.*, 456 U.S. 201, 102 S.Ct. 1650, 72 L.Ed.2d 12 (1982), it found that the statute precluded any judicial review of "determinations of the amount of Part B awards." *Id.* at 208, 102 S.Ct. at 1654. This followed rather straightforwardly from § 1395ff(b)'s provision for review "of any determination . . . as to . . . the amount of benefits under part A", coupled with § 1395ii's incorporation of § 405(h)'s preclusion rule. The Court also noted legislative history indicating congressional concern that otherwise the courts might be flooded with "minor matters". *Id.* at 209, 102 S.Ct. at 1655.

Four years later—but four months *before* Congress amended § 1395ff(b) to extend subsection (1)(C)'s coverage to part B—the Court found that the preclusion as to part B claims did not encompass attacks on the *method* by which the Secretary determined part B amounts. In *Bowen v. Michigan Academy of Family Physicians*, the Court stressed the "strong presumption that Congress intends judicial review of administrative action", 476 U.S. at 670, 106 S.Ct. at 2135, and declined to "indulge the Government's assumption that Congress . . . intended no review at all of substantial statutory and constitutional challenges to the Secretary's administration of Part B", *id.* at 680, 106 S.Ct. at 2141. It called the government's view "extreme", *id.*, and said that its acceptance would raise a "serious constitutional question", *id.* at 681 n. 12, 106 S.Ct. at 2141 n. 12. It also noted its reliance in *Erika*

on legislative history attributing the preclusion of review of part B *amounts* determinations to an expectation that they would involve a horde of trivial claims. *Id.* at 675, 680, 106 S.Ct. at 2138, 2141.

If judicial review of Medicare part B disputes is still governed by the amounts/methodology distinction of *Michigan Academy*, HIC's attacks on § 405.502(g) and on TL 1237 would seem to fall squarely on the methodology side of the line. While ordinary administrative law principles such as the requirement of ripeness might bar some claims, such as the attack on TL 1237, compare *Public Citizen v. NRC*, 940 F.2d 679 (D.C.Cir.1991), they would likely not defeat the district court's jurisdiction.

We think, however, that the October 1986 amendment makes the *Eldridge-Ringer* line of authority the sole determinant of jurisdiction for Medicare claims, both parts A and B. First, it seems inescapable that the same rule must govern parts A and B; the special treatment of part B, based on the pre-October 1986 statutory differences, cannot survive the elimination of those differences. While the House Report accompanying the amendment focused on adding judicial review for part B claimants who previously enjoyed none (i.e., ones asserting only "amounts" claims), it also explained that the amendment established "an appeals procedure under Part B that is modeled after that available under Part A". H.R.Rep. No. 727, 99th Cong., 1st Sess. 95, reprinted in 1986 U.S.C.C.A.N. 3607, 3685. There is, indeed, no difference in the statutory provisions governing judicial review of parts A and B, at least insofar as plaintiffs may be affected.

Accordingly, if the *Michigan Academy* analysis were to still control part B, it would also control part A. That in turn would require a decision that *Michigan Academy* either overruled *Ringer* (sub silentio, as it certainly did not purport to do so) or assumed that it was only an

"amount" case, not a methodology dispute. The latter would be a stretch, however, as *Ringer* revolved around the legality of the Secretary's policy statement expressing her *generic* approach to BCBR (bilateral carotid body resection) operations performed to relieve respiratory distress. See 466 U.S. at 605, 607, 104 S.Ct. at 2016, 2017. Even with this revisionist view of *Ringer*, there would be the question of why the courts should find such a gulf between Social Security (Title II) and Medicare, when Congress seems to have used the first as a template for the second.

Second, as our summary of *Michigan Academy* makes clear, the Court rested the decision largely on the presumption of reviewability, which would have been completely defeated if § 1395ff(b)(1)(C)'s pre-October 1986 exclusion of part B were read to encompass methodology disputes. With the October 1986 amendment, part B claims will not go unreviewed; review simply awaits *initial* administrative determination in a concrete setting.

This is not to say that there are no fragments out of which to construct a contrary argument. HIC discerns help in a provision of the October 1986 amendments, § 1395ff(b)(4), which provides that there shall be no judicial review of a "regulation or instruction which relates to a method for determining the amount of payment under part B" issued before January 1, 1981. 42 U.S.C. § 1395ff (b)(4) (1988). From this it infers an intent to leave methodology claims where *Michigan Academy* put them. But the inference is hardly necessary. The section appears simply to carve out one set of claims—methodology claims based on departmental decisions before 1981—from the general rule that all part B claims, including methodology disputes that arise in disposition of specific, concrete claims, are judicially reviewable under the pattern established by §§ 405(g) & (h).

Appellees also suggest that the legislative history of the October 1986 amendment reflects a focus on affording part

B beneficiaries a better process for resolution of disputes over *amounts*, because of concern about "the fairness and adequacy of [the] Part B appeals process". H.R.Rep. No. 727, 99th Cong., 1st Sess. 95, reprinted in 1986 U.S.C.C.A.N. 3607, 3685. The same passage also notes that the assumption underlying the initial preclusion—that disputes would involve only trivial amounts—had proven unfounded: "Today . . . Part B claims often involve very substantial amounts". *Id.*

Indeed, the legislative history does show a focus on what Congress was affirmatively doing—opening up part B "amounts" determinations to judicial review on the same basis as disputes under part A. The focus is hardly surprising. But it says nothing about whether methodology disputes should continue exempt from the preclusive effect of § 405(h) (imported to Medicare by § 1395ii), once they can be resolved in the § 405(g) format as aspects of concrete disputes over amounts.

We note a passage in *Michigan Academy* that might be thought to provide mild support for appellees' reading. The Court there said that there were "matters which Congress did not delegate to private carriers, such as challenges to the validity of the Secretary's instructions and regulations," 476 U.S. at 680, 106 S.Ct. at 2141, so that these, the Court said, were properly cognizable in courts of law. From this it might be argued that the special role of carriers and intermediaries in Medicare argues for allowing quick end-runs to court. The carriers' role might also answer the question we raised earlier, as to why Congress might have intended a different scheme for Medicare; it might have believed that carriers, as private profit-seeking entities, would be less apt to treat applications fairly and lawfully.[1]

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[1] The inference of systemic differences might depend on the way in which carriers are compensated, which the record does not disclose.

The inference seems weak, however. The October 21, 1986 amendment makes clear that persons affected by an adverse decision of a *carrier* may now obtain review *by the Secretary*, see 42 U.S.C. § 1395ff(b)(1) (1988), so that the administrative structure is plainly available to correct whatever systemic flaws may be ascribed to carriers. Further, the Court in *Michigan Academy* was concerned not with timing, but with reviewability *vel non*. In that context it not unnaturally found an anomaly in consigning final resolution of methodology disputes to entities which lacked the competence or authority to resolve them. Given the October 1986 amendments, however, application of the *Eldridge-Salfi* line to Medicare does not leave methodology disputes in the hands of carriers; it simply means that they are fed through the administrative-judicial system as parts of disputes over actual amounts.

We have addressed this issue at what may seem undue length because we note that some of our sister circuit courts have *assumed* the continued application of *Michigan Academy* to part B Medicare issues. Appellees cite *Bodimetric Health Services v. Aetna Life & Casualty*, 903 F.2d 480 (7th Cir.1990); *Texas Medical Ass'n v. Sullivan*, 875 F.2d 1160 (5th Cir.1989); and *Association of Seat Lift Manufacturers v. Bowen*, 858 F.2d 308, 316-17 (6th Cir.1988). *McCuin v. Secretary of Health & Human Services*, 817 F.2d 161, 164-66, (1st Cir.1987), *Kuritzky v. Blue Shield of Western New York, Inc.*, 850 F.2d 126, 128 (2d Cir.1988), and *Isaacs v. Bowen*, 865 F.2d 468, 471 (2d Cir.1989), are to the same effect. But as *not one* of these cases addresses or even mentions the 1986 amendment, the courts' continued use of the amounts/methodology distinction is not surprising.

Damages and Restitution

Having concluded that the district court lacked jurisdiction to issue its injunction, we turn to the implications for

HHS's quest for damages and restitution. As to damages, a defendant injured by a wrongfully issued preliminary injunction is presumptively entitled to recovery on the injunction bond. As the Seventh Circuit said in *Coyne-Delany Co. v. Capital Dev. Bd.*, 717 F.2d 385 (7th Cir. 1983), this approach is virtually required by the text of Rule 65(c). Although the Rule does not explicitly address the disposition of the bond once the injunction is found wrongful, payment to the injured defendant seems almost inescapable, since the Rule imposes a requirement of security ("in such sum as the court deems proper") for the precise purpose of assuring compensation of the defendant for the resulting losses if the injunction proves to have been wrongfully granted. *Id.* at 390-91. Moreover, the court reasoned, this presumption—the majority view—would make the law "more predictable" than a rule of open-ended judicial discretion and would discourage plaintiffs from seeking preliminary injunctions on weak "though not necessarily frivolous" grounds. *Id.* at 391-92. The preference for allowance of damages is a solid one; it justifies disallowance only where there is "good reason", and does not allow the district court "carte blanche to excuse the plaintiff". *Id.* at 391. We agree with this analysis, except insofar as it understood our previous ruling in *Page Communications Engineers, Inc. v. Frochlke*, 475 F.2d 994 (D.C.Cir.1973), to be incompatible.

In *Page* we rejected a claim that Rule 65(c) automatically entitled defendants to recovery on the bond on a showing of damage, regardless of the equities of the case. *Id.* at 997. We clearly regarded those equities as leaning toward the plaintiff; although we spoke loosely of the plaintiff's "good faith", arguably suggesting that that was enough to negate recovery on the bond, we also noted that the injunction might never have been granted if the government defendant had brought a specific study to the court's attention in a timely fashion. *Id.* Compare *Coyne-Delany*, 717 F.2d at 392 (noting that defendant's failure to mitigate damages could be a good reason to overcome

the presumption in favor of damages within the bond). Accordingly, we do not read *Page* as adopting a maverick view but rather as in accord with the accepted presumption in favor of recovery.

Without that presumption, the bond would fail to accomplish an important goal, that of forcing the plaintiff to consider the injury to be inflicted on its adversary in deciding whether to press ahead in its quest for a preliminary injunction. The deterrence of flimsy claims depends on this. Compare Note, Interlocutory Injunctions and the Injunction Bond, 73 Harv.L.Rev. 333, 342 (1959), making a parallel argument as to the incentives of the *court*: "[T]o eliminate effectively the factor of possible injury to the defendant from those to be considered in determining whether to grant interlocutory relief, the injunction bond must assure the defendant of indemnity in every case in which the injunction issued erroneously." See also Note, Recovery for Wrongful Interlocutory Injunctions Under Rule 65(c), 99 Harv.L.Rev. 828 (1986).

In the exercise of discretion as to enforcement of the bond, the district court clearly disregarded the presumption in favor of recovery, instead placing a burden on defendants to show that recovery was in the interest of equity. See 754 F.Supp. at 904. Its consideration of factors that it regarded as relevant is useful, however, in addressing the proper exercise of discretion under the presumption. It discussed five factors, none of which (alone or in the aggregate) is enough to overcome the presumption. The first two are that the case was brought in good faith and was not frivolous. *Id.* But these are merely baseline premises; if the plaintiff flunks either of them the presumption in favor of enforcement congeals virtually into rock. Compare *Coyne-Delany*, 717 F.2d at 390 (plaintiff's good faith not justification for withholding recovery).

Third, the district court asserted that HIC had received no unjust enrichment; as it received the compelled payments in exchange for dialysis services rendered to pa-

tients, the moneys "were not all profit". 754 F.Supp. at 904. In fact the record does not reveal the size of HIC's profit over the 13 months during which the injunction enabled it to persist in charging Method II rates (double those for Method I) in the face of administrative determinations to the contrary. But in any event the calculation of damages on an injunction bond looks to the injury to defendants, not unjust enrichment of plaintiffs. Any such shift in focus would plainly blunt the bond's incentive effects.

Fourth, the district court suggested that the "public interest" favors encouraging plaintiffs to challenge agencies' interpretations of their governing statutes. *Id.* But this completely overlooks a key purpose of the *bond* and the presumption of enforceability—to make plaintiffs consider the damage they may inflict by pressing ahead with a possibly losing claim. The presumption expresses a judgment that already subsumes such generic policy considerations as the public interest in providing judicial interpretations of statutes.

Finally, the court said that only the passage of a new law by Congress—the Omnibus Budget Reconciliation Act of 1989—caused the injunction to be vacated. While true in a historical sense (passage of the statute led the district court to modify its injunction, and the modification mooted defendants' appeal), the argument is false in a legal sense: our decision that the district court lacked jurisdiction is wholly independent of the intervening statute and depends solely on our reading of the pre-existing statutory provisions for judicial review.[2]

Thus we turn to the calculation of the defendants' damages under the bond. Defendants' position appears to be that the court should simply take the difference between the rate paid under the injunction (about $3000), sub-

[2] Plaintiffs' brief largely tracks the factors mentioned by the district court, see Appellees' Brief at 20-26; to the extent that it invokes additional factors, they do not assist.

tract the capped rate (about $1500), and multiply by the number of patient months. Given HIC's approximately 1000 patients, the calculation leads to a figure vastly exceeding the $750,000 covered by the bond. The method has the virtue of simplicity; further, it corresponds to the way many similar remedies—such as utility rate refunds —are computed.

Plaintiffs' approach is more dynamic. It starts with the proposition that neither it nor others would supply home dialysis if the Method II price were capped at Method I levels. (A more modest version of the proposition, that providers would supply *less* home dialysis if the price were cut from $3000 to $1500, would seem to flow readily from the usual assumption that supply is price elastic.)[3] Moreover, they say, if home dialysis were unavailable, the patients would incur Medicare-reimbursable expenses, such as transportation expenses, *exceeding* the Method I v. II difference in cost. The upshot is the counter-intuitive claim that the injunction *saved* the government money. See Appellees' Brief at 27-28. They further argue that evidence that they put into the record —mainly in the district court's hearing on the proper amount of the bond—supports this view.

The district court never addressed the computation of damages, having decided that for equitable reasons none should be awarded no matter what the correct level. Accordingly, we do not undertake to resolve the

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[3] This is not to say that defendants' theory is necessarily inconsistent with supply being price elastic. One might view HIC as selling its services during the injunction's effective period at the *expected value* of the price—its value weighted in accordance with HIC's estimates of the probabilities of various outcomes. For instance, if they regarded the injunction as having a 50-50 chance of being upheld, and assumed that restitution would be afforded if it were not, then they were selling for (a) a certain $1500, plus (b) a 50-50 chance at another $1500, or a total expected value of $2250. Thus, defendants' theory may be justified as seeing HIC as having sold the services for $1500 plus a gamble that proved to be a losing one.

issues here, but remand the case for the purpose of computing damages to be collected on the bond. The initial step must be a reasoned choice between the two approaches. Clearly there are precedents for both—for defendants', as we noted, public utility rate refunds; for plaintiffs', many complex commercial litigations. See, *e.g.*, *Polaroid Corp. v. Eastman Kodak Co.*, 16 U.S.P.Q.2d 1481 (D.Mass.1990). The district court should make the initial decision as to which is most suitable in the present context.

This brings us to the next issue—whether HHS may recover more than the amount of the bond. The government accepts the proposition that in the absence of plaintiff bad faith or frivolousness, it could not recover *damages* in excess of the bond. See *Coyne-Delany*, 717 F.2d at 393-94. Rather, it argues that a defendant can recover in *restitution* sums not covered by a bond but paid to a plaintiff as a result of a subsequently invalidated injunction, citing (among other cases) *Arkadelphia Milling Co. v. St. Louis S.W. Ry. Co.*, 249 U.S. 134, 39 S.Ct. 237, 63 L.Ed. 517 (1919), and *Mitchell v. Riegel Textile, Inc.*, 259 F.2d 954, 955 (D.C.Cir.1958); see also *Coyne-Delany*, 717 F.2d at 393 (noting the possibility and citing *Mitchell*).

HIC argues that the precedents do not support restitution in these circumstances. While it seems to concede that restitution is not governed by the rule capping damages at the level of the bond, it distinguishes both *Arkadelphia* and *Mitchell* as cases where the amount recoverable in restitution was clearly ascertainable. Appellee's Brief at 29-30. Here, by contrast, HHS received Method II services in exchange for the payments, conceivably of value equal to the charge. Further, in *Arkadelphia*, the injunction had been issued under an explicit provision for "refund in every instance". 249 U.S. at 138, 39 S.Ct. at 239.

Neither of these distinctions works. It simply is not a principle of restitution that it is available only when

the sums are indisputable. For example, almost any restitution for performance of services, see *Restatement of Restitution* § 40, will require calculation of the reasonable value of the services. For examples as to benefits conferred under a judgment, see *United States v. 3,317.39 Acres of Land, More or Less, in Jefferson County, Arkansas*, 481 F.2d 417, 419-20 (8th Cir.1973); *Kane v. Motor Vessel Leda*, 355 F.Supp. 796, 801-05 (E.D.La. 1972), aff'd, 491 F.2d 899 (5th Cir.1974). Moreover, in both *Arkadelphia* and *Mitchell* the restitution was set in the context of an *exchange* (in *Arkadelphia*, money in exchange for railway services; in *Mitchell*, money in exchange for labor services). Obviously it was open to the plaintiff to have asserted, as plaintiffs have here, that without the injunction the amount of services supplied and purchased would have been different. In neither case did the court hint that such an assertion would have induced it to back away from awarding restitution. Indeed, were that the rule, plaintiffs (and others subject to restitution) could often escape it at will.[4]

Similarly, while it is true that in *Mitchell* the parties agreed on the amount of the underpayments (certain textile mills had secured an injunction allowing them to pay their workers *less* than a statutory minimum), see 259 F.2d at 955, we placed no reliance on the point. Any restitution principle would be severely undermined if its enforcement depended on the parties' prior agreement as to the precise amounts involved. Finally, while in *Arkadelphia* there was prior provision for reimbursement, the Court did not rely on it and to have done so would have drastically narrowed the principle of restitution.

We need not here address the exact formulae for restitution. Under the Medicare legislation HHS has established elaborate procedures for recoupment of overpay-

[4] More generally, where a party raises elasticities of supply or demand in disputed computations of restitution, both the complexity of the resulting calculation, and the point noted in footnote 3, might militate against considering their possible effect.

ments to suppliers. See generally *Chaves County Home Health Service, Inc. v. Sullivan*, 931 F.2d 914 (D.C.Cir. 1991). While the parties have not briefed the substantive principles of recoupment, HHS asks only that the district court order be removed as an impediment to their application. To the extent that those substantive principles (1) accord with HHS's statutory authority and (2) are properly applicable to overpayments of the sort involved here (as HHS implicitly asserts), they would appear to control. Accordingly, we vacate the district court judgment to the extent that it purports to interfere with HHS's application of its recoupment procedures. When those procedures have run their full course, HIC may, if not content with the outcome, seek judicial relief in an appropriate forum.

Accordingly, the judgment of the district court is reversed and the case remanded to it solely for resolution of the dispute over the amount of damages that defendants may recover under the bond.

So ordered.

APPENDIX B

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Civil Action No. 88-3251 SS

NATIONAL KIDNEY PATIENTS ASSOCIATION, *et al.*,
Plaintiffs,

v.

OTIS R. BOWEN, Secretary, Department of Health and Human Services, *et al.*,
Defendants.

MEMORANDUM OPINION

[Filed Jan. 17, 1991]

This case is now before the Court after a protracted series of proceedings. The plaintiffs filed suit in 1988 seeking to prevent the Health Care Financing Association ("HCFA") from lowering reimbursement rates for certain services covered by Medicare. On December 22, 1988, this Court issued a preliminary order enjoining the rate reduction. The Court of Appeals subsequently vacated the preliminary injunction after Congress passed a law that rendered the injunction moot. The sole issue remaining before the Court is the disposition of a $750,000 surety bond posted by plaintiff Home Intensive Care, Inc. ("HIC") in connection with the preliminary injunction. Because the injunction was not erroneously granted, and in any event because the balance of equitable factors favors the plaintiffs, the bond will be returned to HIC.

I. Background

Plaintiffs in this case are individual patients suffering from end stage renal disease, the National Kidney Patients Association, which represents such patients, and HIC, a company that provides at-home renal dialysis

treatments to such patients. End stage renal disease—the permanent breakdown of the kidneys' disposal function—is invariably fatal unless the patient receives regular renal dialysis treatments. To help defray the enormous expense of dialysis, Congress in 1972 extended Medicare Part B coverage to dialysis treatments. *See* 42 U.S.C. § 1395rr. Medicare Part B is administered by HCFA, which is part of the Department of Health and Human Services ("HHS"). HCFA is authorized, however, to contract with private insurers to actually perform reimbursement services. Under 42 C.F.R. § 405.502 (a)(7), these private carriers are authorized to reduce a provider's requested reimbursement if it is "inherently unreasonable." Defendants are the Secretary of HHS, the Administrator of HCFA, and one of these private carriers.

The Medicare statute provides two methods for calculating the reimbursement rate for dialysis treatments. Method I is used for treatments in clinics or hospitals. Under Method I, HCFA establishes a "composite rate" based on the average regional cost of dialysis treatments for patients receiving care in clinics. *See* 42 U.S.C. § 1395rr(b)(3). All clinics within each region receive reimbursement at this composite Method I rate.

Method II is used for dialysis treatments administered in the patient's home. *See* 42 U.S.C. §§ 1395rr(b)(7). At the time this suit was initiated, Method II called for reimbursement to individual home dialysis patients of the "reasonable" cost of purchasing dialysis equipment and supplies. Historically, Method II provided benefits more generous than those available under Method I.

Most end stage renal disease patients receive dialysis treatments at clinics, which are reimbursed according to Method I. Home dialysis, accompanied by the higher Method II reimbursement rate, has traditionally been provided only to patients with extraordinary medical necessity. In 1985, HIC began to provide home dialysis

on a routine commercial basis. While the home treatments provided by HIC were more costly than clinic-based dialysis, HIC was able to use the higher Method II payments to pay for medical technicians and equipment, and still earn a profit. HIC's system became an immediate success. At an evidentiary hearing on plaintiffs' motion for a preliminary injunction, plaintiffs introduced overwhelming evidence that home dialysis is less risky and less disruptive for patients than treatment in clinics, and that home dialysis enables patients to lead more productive lives.

Nonetheless, HCFA disapproved of the HIC system, taking the position that home dialysis is too costly and should be reserved for extraordinary cases. To reduce costs, HCFA issued Transmittal 1237 to Medicare carriers. Transmittal 1237 in effect limited reimbursements for home dialysis treatments to the Method I level, unless special medical circumstances mandated home dialysis. HCFA's stated rationale for this limitation was that all dialysis charges above the Method I level were unreasonable.

Plaintiffs instituted this action to challenge HCFA's issuance of Transmittal 1237 and the carriers' implementation of it. They argued that Transmittal 1237 was arbitrary and capricious, that it was contrary to the Medicare statute, that its issuance suffered from procedural defects, and that the carriers lacked authority to implement it. After an extended evidentiary hearing, this Court on December 22, 1988, entered a preliminary injunction prohibiting HCFA and the carriers "from reducing the rate of reimbursement under Medicare, Part B, Method II for Home Hemodialysis." Upon the defendants' motion, the Court required HIC to post a surety bond in the amount of $1,000.

Defendants appealed both the preliminary injunction and the bond. In a one-page, *per curiam* order dated December 8, 1989, the Court of Appeals held that the HIC

bond was "'[in]sufficient to protect [its] adversary from loss in the event that future proceedings prove that the injunction issued wrongfully'" (quoting *Edgar v. Mite Corp.*, 457 U.S. 624, 649 (1982) (Stevens, J., concurring)). On remand from the Court of Appeals, this Court set HIC's bond at $750,000.

While defendants' appeal of the preliminary injunction was pending before the Court of Appeals, Congress enacted the Omnibus Budget Reconciliation Act of 1989 ("OBRA"), Pub. L. No. 101-239. Section 6203(b)(1) of this statute amended 42 U.S.C. § 1395rr(b)(7) to provide that Medicare reimbursement for home dialysis treatments "may not exceed the amount . . . of the median payment that would have been made under the formula for hospital-based facilities." This provision reduced Method II payments to the Method I level. Congress effected by statute precisely what HCFA had sought to accomplish with its Transmittal 1237. Subsequently, the Court of Appeals dismissed defendants' appeal as moot, vacated the preliminary injunction, and remanded the case to this Court. *National Kidney Patients Association v. Sullivan*, 902 F.2d 51 (D.C. Cir. 1990).

II. Mootness

Plaintiffs' complaint is now moot. The enactment of OBRA obviated Transmittal 1237. Plaintiffs' challenge to Transmittal 1237 no longer presents this Court with anything to decide. Plaintiffs' objections to the reimbursement schedule effected by Transmittal 1237 were based on statutory and procedural grounds. Because Congress passed a statute that in effect enacted Transmittal 1237 into law, these objections are no longer tenable. Congress' action has precluded plaintiffs from obtaining the relief they originally sought. Plaintiffs themselves concede that they have no basis upon which to request any future relief. *See* Memorandum of Points and Authorities in Support of Plaintiffs' Motion for Summary Judg-

ment at 2. Plaintiffs' action has been rendered moot and their complaint will be dismissed.

III. Disposition of Plaintiff's Surety Bond

The dismissal of plaintiffs' complaint leaves one issue remaining in the case: whether the government is entitled to recover from plaintiffs damages for the wrongful issuance of an injunction. Defendants have made a claim for $18 million which they assert represents the amount HCFA was forced to spend on home dialysis reimbursements above the Method I level during the life of the preliminary injunction. Defendants cannot recover damages, however, in excess of the surety bond posted by plaintiffs. *See W.R. Grace & Co. v. Local Union 759*, 461 U.S. 757, 770 (1983) ("A party injured by the issuance of an injunction later determined to be erroneous has no action for damages in the absence of a bond."); *Matek v. Murat*, 862 F.2d 720, 733 (9th Cir. 1988) ("the limit of damages a party can obtain for wrongful injunction . . . is the amount of the bond"). The issue before the Court, then, is the disposition of HIC's $750,000 bond.

A. The Propriety of the Preliminary Injunction

The Court ordered plaintiffs to post a bond pursuant to Fed. R. Civ. Pro. 65(c), which provides:

> No restraining order or preliminary injunction shall issue except upon the giving of security by the applicant, in such sum as the court deems proper, for the payment of such costs and damages as may be incurred or suffered by any party who is found to have been wrongfully enjoined or restrained.

See also Monzillo v. Biller, 735 F.2d 1456, 1461 (D.C. Cir. 1984) ("The purpose of the security requirement [of Rule 65(c)] is to protect a party from damages suffered if it is later determined that the preliminary relief was wrongfully granted."). This provision does not entitle

defendants to the bond proceeds. The preliminary injunction in this case was not wrongfully granted. Even if it was, equitable considerations militate against forfeiture.

Defendants may recover a Rule 65(c) bond only after a showing that the underlying injunction was improper. The government has argued, both in its initial opposition to the plaintiffs' motion for a preliminary injunction and again in support of its claim to the bond, that this Court had no jurisdiction to grant the plaintiffs injunctive relief. But when this Court issued the injunction, it held explicitly that it did have jurisdiction to hear plaintiffs' claims. *See* Bench Opinion delivered on December 22, 1988, at 740-41 [hereinafter Bench Opinion]. That holding remains the law of this case. The Court of Appeals vacated the preliminary injunction not because it determined that the injunction had been erroneously granted but because Congress changed the law. This Court could award defendants the bond only by completely reversing its earlier jurisdictional determination. Nothing in the defendants' argument has persuaded the Court to do so.

Apart from its jurisdictional argument, the government contends that the Court's decision to issue the injunction was wrong on the merits. Defendants point to the enactment of OBRA in support of this argument. According to defendants, Congress by enacting OBRA has declared this Court's earlier interpretation of 42 U.S.C. § 1395rr(b)(7) to be erroneous. The Court draws precisely the opposite conclusion from Congress' action. Congress has indeed "overruled" the Court. It has done so by changing the law, which it has the absolute right to do. Congress' decision to amend the Medicare statute, however, does not imply that prior to OBRA plaintiffs did not have the right to Method II reimbursement. OBRA's amendment of the Medicare statute was prospective. While Congress could have given the statute retroactive effect, it chose not to do so. In fact, Congress directed

that OBRA would not take immediate effect, providing instead for a transition period of more than a month following the law's enactment. If Congress' action said anything about the meaning of the law at the time the injunction was granted, it said that the Court's understanding of the statute was correct. The Court continues to believe that the injunction was proper at the time it was granted. This alone provides sufficient justification for returning the bond to plaintiffs.

B. The Standard for Forfeiture of a Bond

Even assuming for the sake of argument that the injunction was erroneously granted, the government would still not be entitled to recover the bond. A Rule 65(c) forfeiture inquiry does not end with a determination that an injunction was improper. The court must then make an equitable judgment as to the disposition of the bond.

Defendants have taken the contrary position that a surety bond posted in connection with a preliminary injunction is automatically forfeited upon a finding that the injunction was wrongfully granted. The U.S. Court of Appeals for the District of Columbia Circuit expressly rejected this position in *Page Communications Engineers, Inc. v. Froehlke*, 475 F.2d 994, 996 (D.C. Cir. 1973) (per curiam):

> Although Rule 65(c) required a bond here, it does not follow that the District Court was bound to award damages on the bond, without considering the equities of the case. The Rule did not make judgment on the bond automatic, upon a showing of damage. On the contrary, the court in considering the matter of damages was exercising its equity powers, and was bound to effect justice between the parties, avoiding any result that would be inequitable or oppressive for either party.

See also, e.g., H&R Block, Inc. v. McCaslin, 541 F.2d 1098, 1099 (5th Cir. 1976) ("The awarding of damages

pursuant to an injunction bond rests in the sound discretion of the court's equity jurisdiction."), *cert. denied*, 430 U.S. 946 (1977); *Coyne-Delany Co. v. Capital Development Board*, 717 F.2d 385, 390 (7th Cir. 1983) ("the district court has unquestioned power . . . not to award damages on an injunction bond even though the grant of the injunction was reversed) (opinion of Posner, J.).

Under *Page Communications*, if a court determines that an injunction has been erroneously granted, the prevailing party must then demonstrate that an award of damages would be "in the interest of equity and justice." 475 F.2d at 996. The government has failed to make such a showing in this case.

C. The Balance of Equitable Factors

Courts have looked to several equitable factors in deciding whether to forfeit an injunction bond. These factors include the plaintiffs' good faith in seeking injunctive relief, the strength of plaintiffs' argument on the merits, the extent of plaintiffs' unjust enrichment, the public interest, and the reason for dissolution of the injunction. All of these factors favor the plaintiffs in this case.

First, the plaintiffs acted with good faith in initiating this lawsuit. Defendants concede, as they must, that this suit arose out of a genuine legal dispute, rather than as an attempt by plaintiffs to harass the defendants or to gain a bargaining advantage. In the "absence of bad faith" on the part of the plaintiffs, the defendants' entitlement to damages is considerably lessened. *Coyne-Delany*, 717 F.2d at 392.

Second, this "was not a frivolous lawsuit." *Page Communications Engineers*, 475 F.2d at 997. The plaintiffs' view of the Medicare statute was certainly well-founded. Indeed, this Court endorsed the plaintiffs' position when it issued the injunction. Defendants based their objection

to the injunction not on the validity of Transmittal 1237 but on this Court's alleged lack of jurisdiction to review HCFA's action. This jurisdictional challenge did not in any way discredit the plaintiffs' arguments on the merits. When a plaintiff brings a case as strong as the one presented by plaintiffs in this case, the sound exercise of this Court's equitable discretion counsels against forfeiture.

Third, plaintiffs in this case have not been unjustly enriched by the preliminary injunction. Defendants point out that the injunction allowed HIC to obtain higher Medicare reimbursements than would otherwise have been available, and the government seeks the return of these payments. These payments were not all profit to HIC. They were used by HIC to finance home dialysis treatments for renal disease patients. HIC established in the preliminary injunction hearing that it would not be able to provide home dialysis treatments without Method II payments. Far from correcting an unjust enrichment, awarding the government damages would leave HIC worse off than it would have been had the injunction been denied in the first place. If HIC's bond is forfeited, HIC would be in the position of having spent money to provide dialysis services without being able to obtain reimbursement.

Fourth, the public interest is best served in this case by returning the bond to plaintiffs. This Court does not want to discourage litigants from challenging agencies' interpretations of their governing statutes, or from contesting the legality of regulations used to implement these interpretations. The Court does not wish to penalize HIC for seeking creatively to expand the quality and quantity of services available under a government benefits program. HIC attempted, within the law, to provide to renal disease patients a treatment that, according to the overwhelming evidence it introduced at the preliminary injunction hearing, is safer for patients and enables them to lead more productive lives. HIC should not have to pay for an after-the-fact decision to preclude such treatments.

The fifth and most important factor in this case is that the preliminary injunction was vacated due to the passage of a new law. Numerous courts have found that "a change in the law that took place after the preliminary injunction was issued" provides sufficient grounds for refusal to award damages on the injunction bond. *Zenith Radio Corp. v. United States*, 823 F.2d 518, 522 (Fed. Cir. 1987); *see also State of Kansas ex rel Stephan v. Adams*, 705 F.2d 1267, 1270 (10th Cir. 1983) ("intervention of Congress" argues strongly against bond forfeiture); *Coyne-Delany Co. v. Capital Development Board*, *supra*.

Against the overwhelming weight of these factors, defendants make three arguments in favor of forfeiture. First, defendants argue that the Court of Appeals has in effect already declared the government's entitlement to the bond. Defendants note that this Court initially set the HIC bond at $1,000, and that the Court of Appeals subsequently ordered this Court to set a higher bond. Defendants suggest that the Court of Appeals would not have bothered to require the increased bond if it did not believe that defendants would be entitled to the bond upon a dissolution of the injunction.

Defendants make too much of the one-page, *per curiam* Court of Appeals order. The Court of Appeals was simply telling this Court that Rule 65(c) requires more than a nominal bond. The Court of Appeals did not address the question whether the bond would later be forfeited. It could not have addressed that question because the issue was not before the Court of Appeals at that time. The only time that issue was arguably before the Court of Appeals was when the injunction was vacated—at which time the Court of Appeals remanded the case to this Court for, among other things, a disposition of the bond. It was plainly the intention of the Court of Appeals that this Court should determine whether to forfeit the bond.

Defendants' second argument is that, in light of OBRA's clear statement of congressional intention that Medicare should not pay for home dialysis, Congress should be understood as having disapproved past payments to HIC. As discussed above, *see supra* p. 7, defendants misunderstand the implications of OBRA. Congress gave OBRA only prospective effect. It left the Method II reimbursement rules in place for someone and one-half months after OBRA's passage. Congress' decision not to make its Medicare amendment retroactive signals, if anything, a recognition that the pre-existing statutory framework gave HIC a right to the Method II reimbursement rate for home dialysis.

Finally, the government relies heavily upon the Supreme Court's decision in *Arkadelphia Milling Co. v. St. Louis Southwestern Railway*, 249 U.S. 134 (1919). At the outset, it is worth noting that *Arkadelphia* was decided in 1919, well before the promulgation of the Federal Rules of Civil Procedure, and it therefore cannot provide an authoritative interpretation of Rule 65(c). Even accepting fully its authority, *Arkadelphia* provides little support for defendants' position.

Arkadelphia involved a challenge by two railroads to rate limitations imposed by a state commission. The trial court accepted the railroads' contentions and issued an injunction against enforcement of the limitations. The court included in its injunction, however, a requirement that the railroads post a bond and that they maintain records of all passengers and freight travelling under rates that would have been prohibited by the commission. The injunction further provided that

> if it should eventually be decided that so much of the order as inhibited the enforcement of the rates ought not to have been made, the [railroads] should within a reasonable time to be fixed by the court refund in every instance to the party entitled the excess in

> charge over what would have been charged had the inhibited rates been applied.

Id. at 138.

The Supreme Court reversed the grant of injunction and remanded the case to the trial court. The trial court then ordered the railroads to make compensation to overcharged passengers, and appointed a special master to oversee the compensation process. The railroads appealed this order to the Supreme Court. The Supreme Court, in the *Arkadelphia* opinion, upheld the trial court's plan, although it modified a few of the details.

Defendants' reliance on *Arkadelphia* is misplaced. The issue in *Arkadelphia* was whether the trial court had the power to impose its restitution regime on the railroads, not whether the overcharged passengers had a right to compensation. The primary teaching of *Arkadelphia*, then, is that a trial court has discretion "consistent with the principles of equity" to use an injunction bond to do justice between the parties. *Id.* at 145. The case can in no way be read to stand for the proposition that every dissolution of an injunction gives rise to a right to damages.

Even as a precedent for the proper exercise of equitable discretion, *Arkadelphia* is inapposite. The remedy ordered in *Arkadelphia* was part of the injunction itself. The trial court was willing to exercise its equitable powers to enjoin the commission's rates only on condition that passengers be guaranteed against overcharging. This Court imposed no such conditions on its injunction in this case. In fact, in ordering preliminary relief for plaintiffs the Court explicitly addressed the possibility that plaintiffs would not prevail after a full trial. In that event, the Court stated, its eventual holding would "be a prospective decision." Bench Opinion at 757. The Court made it clear from the beginning that HIC would not be held responsible for additional Medicare expenses result-

ing from the Court's preliminary ruling. Unlike *Arkadelphia*, then, plaintiffs in this case relied on the preliminary injunction to provide services that they otherwise would not have provided. In contrast, the railroads in *Arkadelphia* were on notice from the outset that, if they chose during the period while the case was pending before the Supreme Court to charge rates in excess of the commission's limits, they might later be required to make compensatory payments. Another crucial difference is that the injunction in *Arkadelphia*, unlike the injunction in this case, was reversed on the merits. *Arkadelphia*, in short, is entirely distinguishable from the instant case, and nothing in it is contrary to this Court's decision to return the surety bond in this case to HIC.

Defendants' request for forfeiture will be denied. The preliminary injunction in this case was not erroneously granted. It was vacated because Congress changed the statute upon which the injunction rested. Even if the injunction is assumed to have been erroneously granted, it is this Court's finding that in balancing the equitable factors plaintiffs' position must prevail.

An appropriate order accompanies this opinion.

DATE: 1/17/91

/s/ Stanley Sporkin
STANLEY SPORKIN
United States District Court

APPENDIX C

UNITED STATES COURT OF APPEALS
DISTRICT OF COLUMBIA CIRCUIT

Nos. 89-5039, 89-5040

NATIONAL KIDNEY PATIENTS ASS'N, *et al.*,
Appellees,

v.

LOUIS W. SULLIVAN, M.D., *et al.*,
Appellants.

Appeal from the United States District Court
for the District of Columbia

Argued Dec. 4, 1989

Decided April 24, 1990

Before WALD, Chief Judge, MIKVA, Circuit Judge, and OBERDORFER, District Judge.*

Opinion for the Court filed PER CURIAM.

PER CURIAM:

This case arises from a dispute over the administration of Medicare Part B payments for renal dialysis treatment. Plaintiffs below, an association of dialysis

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* The Honorable Louis F. Oberdorfer of the United States District Court for the District of Columbia, sitting by designation pursuant to 28 U.S.C. § 292(a) (1982).

patients and dialysis suppliers, sought to enjoin the Department of Health and Human Services ("HHS") and a local insurance carrier, Blue Cross and Blue Shield of Florida, Inc. ("Blue Cross"), from reducing medicare reimbursements for home dialysis treatment to the level set for clinical treatment. The district court granted the plaintiffs a preliminary injunction. The court found that plaintiffs would suffer irreparable injury without a preliminary injunction and ruled that they would likely prevail on each of their independent claims for permanent injunctive relief. HHS and Blue Cross appealed this decision on the ground that the preliminary injunction was improvidently granted. For the reasons stated below, we find the appeal is moot. Accordingly, we vacate the injunction and remand the case to the district court.

I. Background

End Stage Renal Disease ("ESRD") is a permanent breakdown of the kidneys' disposal function which, without regular dialysis treatment, will cause a patient to die within a matter of days. The dialysis necessary to sustain an ESRD patient's life, however, is extremely expensive, costing over $20,000 per year. To help defray these costs, Congress in 1972 extended Medicare Part B coverage to dialysis treatment for ESRD patients. 42 U.S.C. § 1395rr.

Congress established two methods of reimbursement for patients who require dialysis treatment—one calculated for clinics ("Method I") and the other calculated for home dialysis ("Method II"). Under Method I, the Health Care Financing Administration ("HCFA")—which is responsible for administering Medicare payments for dialysis beneficiaries—and HHS promulgate a "composite rate" based on the average regional costs of dialysis treatment for patients receiving care in dialysis clinics. 42 U.S.C. § 1395rr (1989). Method I reimbursement applies only where a patient receives dialysis treatment

through a clinic (including home dialysis provided by clinical staff). By contrast, Method II reimburses a patient for the actual cost of purchasing dialysis equipment and supplies for home use up to a "reasonable amount." 42 U.S.C. § 1395rr(b)(1)(B) (1989).

The Medicare statute authorizes HCFA to contract with private insurers ("carriers") who handle the administrative details of Part B reimbursement. The carriers determine, *inter alia*, whether a service or item is covered and establish the reasonable charge that may be paid for these services and items. 42 U.S.C. § 1395u(a) (1989); 42 C.F.R. §§ 405.803, 421.200 (1988). In 1985, HHS amended its regulations to permit carriers to modify "inherently unreasonable" charges. 42 C.F.R. § 405.502 (a)(7) (1988).

In 1986, HCFA issued Transmittal 1237 which directed carriers to exercise their power to modify Part B charges that are inherently unreasonable or to explain why current levels were reasonable. The Transmittal stated that many carriers were permitting charges in excess of the composite rate (Method I). It suggested that any charge in excess of the Method I rate was suspect, since Method I rates cover expenses such as staff assistance that are not included under Method II.

In response to the Transmittal, appellee Blue Cross determined that its current Method II rate for home dialysis suppliers was "inherently unreasonable" and proposed to reduce its Method II payment ceiling to $1,625 per month for home hemodialysis, approximately the same rate as Method I. As a result, appellee, Home Intensive Care ("HIC"), a home hemodialysis provider, would have its yearly reimbursement for ESRD patients reduced from $37 million to $19.5 million.

In their suit for preliminary and permanent injunctive relief, HIC and the other appellees alleged that Blue Cross' reduction of Method II rates to the Method I level

was both substantively impermissible and procedurally defective. Specifically, they alleged that: (1) they had a statutory right to have Method II payments calculated independently of the Method I option; (2) Blue Cross lacked authority to make inherent unreasonableness determinations because that power had never been subjected to proper notice and comment prior to its promulgation; (3) the determination that Method I and Method II rates should be the same was not based upon actual expenses and hence was arbitrary and capricious; and (4) the Transmittal was not properly subjected to notice and comment proceedings.

The district court found that the plaintiffs were likely to succeed on each of these claims, and accordingly it issued a preliminary injunction to prevent any irreparable injury that might arise from enforcement of Blue Cross' action. The appellants challenged the district court's decision on the grounds that the Transmittal was not a change in substantive policy with all the attendant procedural protections; HCFA and Blue Cross did not act arbitrarily in using Method I as a benchmark; and the district court lacked jurisdiction over this action.

While our decision in this case was still pending, Congress enacted the Omnibus Budget Reconciliation Act of 1989 ("OBRA"). OBRA Section 6203(b)(1), which amends 42 U.S.C. § 1395rr(b)(7), accomplishes precisely what was enjoined by the trial court; it limits the amount of payment for hemodialysis equipment and supplies under Method II to the composite Method I rate received by hospital-based facilities.

II. Mootness

This court's first task on review is to determine whether OBRA Section 6203(b)(1) has mooted the issue raised on appeal. *Brown v. Chote*, 411 U.S. 452, 457, 93 S.Ct. 1732, 1735, 36 L.Ed.2d 420 (1973). The sole issue on appeal to this court is whether the district court abused

its discretion in granting appellees' motion for a preliminary injunction. Both parties concede, however, that that injunction is no longer effective. Under OBRA Section 6203(b)(1), HHS may calculate home-dialysis reimbursements in precisely the manner previously prohibited by the district court's injunction.

The scope of our review of a preliminary injunction that has expired while on appeal is controlled by the Supreme Court's decision in *University of Texas v. Camenisch*,, 451 U.S. 390, 394-95, 101 S.Ct. 1830, 1833-34, 68 L.Ed.2d 175 (1980). In *Camenisch*, a deaf graduate student obtained a preliminary injunction which directed the University of Texas to appoint a sign-language interpreter for him. The University obeyed the injunction, and while its appeal was pending, Camenisch graduated. The Supreme Court determined that the appeal was moot. The Court observed that the issue raised before the appeals court— namely, whether the District Court abused its discretion in issuing a preliminary injunction —was no longer a live controversy "because the terms of the injunction . . . ha[d] been fully and irrevocably carried out." 451 U.S. at 398, 101 S.Ct. at 1835.

Our situation is indistinguishable from that in *Camenisch*. The injunction challenged by appellants enjoined HCFA from imposing its new reimbursement rules, at least until Congress intervened. When Congress enacted OBRA on February 1 of this year, the terms of the preliminary injunction were "fully and irrevocably carried out." The relief sought and granted by the district court, then, expired on its own terms.

Appellants nevertheless contend that the *case* is not moot because a live issue remains about whether HIC or HHS should bear the cost of payments made in excess of the Method I rates while the injunction was in effect. A nearly identical claim was expressly rejected by the *Camenisch* Court. The Court cautioned that an appeals court may consider only the *issue* raised before it, and

that the question of who should bear the cost of a now-moot injunction was "significantly different" from the issue of whether the injunction was improvidently granted. 451 U.S. at 393, 101 S.Ct. at 1833. Accordingly, in *Camenisch*, the Court remanded the case to the district court for a trial on the merits to determine who should ultimately bear the cost of the interpreter. *Id.* at 398, 101 S.Ct. at 1835.

Appellants' other attempts to breathe life into their perished appeal are equally unavailing. The fact that the federal defendants base their appeal in part on a challenge to the district court's jurisdiction cannot save their claim. An appellate court may only review final, appealable orders of a district court. *Catlin v. United States*, 324 U.S. 229, 236, 65 S.Ct. 631, 635, 89 L.Ed. 911 (1945); *Save the Bay, Inc. v. United States Army*, 639 F.2d 1100, 1103 (5th Cir.1981). As noted, the district court's order must be vacated and thus is no longer susceptible to appellate review. The threshold issue of subject-matter jurisdiction may be determined only after a final judgment on the merits is presented to us.

Likewise, appellants' observation that HIC may still submit claims based on services rendered during the pre-OBRA period does not resuscitate their appeal. The injunction challenged here involved only the incurrence of reimbursable expenses; all such expenses had been incurred at the time OBRA was enacted. As we noted, the recoupment of any reimbursement for those expenses—or actions to avoid payment of outstanding reimbursable expenses—was not presented on appeal. *See Camenisch, supra*, 451 U.S. at 394-95, 101 S.Ct. at 1833-34. Those claims must first be determined by the trial court on the merits before they can furnish a basis for appellate review. *Honig v. Students of the California School for the Blind*, 471 U.S. 148, 105 S.Ct. 1820, 85 L.Ed.2d 114 (1985).

III. Conclusion

The only issue presently before us—the correctness of the decision to grant a preliminary injunction—is no longer justiciable. Accordingly, the appeal is dismissed, the judgment of the district court is vacated, and the case is remanded to the trial court for further proceedings. *Honig, supra*, 471 U.S. at 149-50, 105 S.Ct. at 1820-21; *Lewis v. Continental Bank Corp.*, —— U.S. ——, 110 S.Ct. 1249, 108 L.Ed.2d 400 (1990).

So ordered.

APPENDIX D

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Docket No. CA 88-3251

NATIONAL KIDNEY PATIENTS ASSOCIATION, *et al.*,
Plaintiffs,

vs.

OTIS R. BOWEN, *et al.*,
Defendants.

Washington, D.C.
December 22, 1988
9:15 a.m.

TRANSCRIPT OF EVIDENTIARY HEARING
BEFORE THE HONORABLE STANLEY SPORKIN
UNITED STATES DISTRICT JUDGE

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* * * *

[736] THE COURT: All right.

Let me—all right. I've heard evidence. By the way, I must tell you that the only reason I'm ruling at this time is because I feel compelled to because of what plaintiffs have stated and the fact that I can't get an appropriate bridge order to take us into the permanent injunction. That means I've had to make certain determinations and I understand that these determinations are made on a fairly sparse record. But that's all that is

before me, and I don't have anything that other—I can't do anything else.

And so based upon that record, I'm going to make my determination, but it is understood that these are preliminary determinations and they will not—they may not, not they will not, but they may not survive the determination on the final hearing.

I do want to compliment all the parties here, because I do think that we have been operating under very trying circumstances and it is very difficult to be able to [737] try a case like this in the time we've tried it, and also do 18 other things, and if I've expressed some frustration, it's because I've been trying to complete this matter.

Well, I've heard evidence at an evidentiary hearing held on December 20, 21, and 22. In addition, hearings were held on November 14, December 7 and December 9, 1988. Based on those hearings, the briefs submitted and the entire record in this case, I'm now prepared to rule on plaintiffs' motion for a preliminary injunction and to make the necessary findings of fact and conclusions of law that are required of me.

This is going to be—I've really patched things together here, so this might not be the most articulate opinion I've ever written, but the necessities of the case require that I give it the way—the best I can.

This case involves plaintiff, Home Intensive Care, as well as other plaintiffs who are seeking to continue with certain in-home hemodialysis treatment that is being provided by the plaintiff, HIC.

Basically the case involves action taken by the Home Care Financing Administration and Florida Blue Cross-Blue Shield in administering payments under Medicare Part B for renal dialysis treatment. Currently under Medicare Part B, there are two methods of payment for dialysis treatment. First, Method 1 provides for a fixed composite rate determined [738] on an averaging basis. Generally most patients receive dialysis treatment at a clinic with payment being made under Method 1.

Congress, however, has provided for a payment system outside the composite rate method, and this is known as reimbursement under Method 2. Method 2 specifically provides for payment for home dialysis supplies and equipment. Method 2 is designed to address unique circumstances that arise in providing and maintaining dialysis service.

Method 2 pays for 80 percent of the reasonable charges for patient supplies and equipment. The patient or his private insurer pays for the remaining 20 percent. By statute reasonable charges are determined by the lowest of either one, the price actually charged by the supplier; two, the customary charge by that supplier; or three, the prevailing charge for suppliers in that area.

Starting in 1985, plaintiff, Home Intensive Care, came up with the idea of providing home dialysis on a routine basis. Under the HIC system, a staff assistant is provided to administer dialysis treatment. The plan was ultimately approved by the Health Care Finance Administration. Originally billing was provided on a Method 1 basis. However, in 1986, HIC organized its program to provide services under Method 2. HIC came to the conclusion that it would be better for itself, and in terms of improving patient care to provide [739] home dialysis under Method 2.

Although Method 2 only provides reimbursement for supplies and equipment, HIC's founder, Dr. Allen Jacob, testified that he determined that because of the billing structure, not only could he provide service and equipment, but he would also be able to absorb the cost for providing an in-home caregiver. That is a professional who administers the dialysis treatment.

In testimony that I heard, it is quite clear that a caregiver is virtually in all instances a necessary element in providing acceptable home dialysis treatment. It must be stressed that in establishing the reasonable basis for its reimbursement, HIC acted in accordance with statutory and regulatory guidelines and in accordance with

Florida Blue Cross-Blue Shield billing practices. This level of payment was accepted not only by Florida Blue Cross, but by the Home Care Financing Administration which continued to reimburse HIC for its services.

Further, the Government concedes that the level at which HIC was reimbursed is identical to the level of reimbursement that an individual who privately contracted with medical suppliers for dialysis equipment and supplies would be reimbursed under Method 2 as during the period of time it has existed.

It seems, however, the plaintiff, HIC, was able to [740] provide identical services at a lower cost, and I should point out that it is quite clear that HIC had nothing to do with the determination of the costs that it was to be reimbursed. These were determined by Florida Blue Cross-Blue Shield. Indeed, all that HIC requested was reimbursement for prices that had been established 15 years ago.

From the savings that HIC was able to obtain, it absorbed the cost of the caregiver. I should point out it is quite clear that unless the plaintiff, HIC, was able to absorb these costs, it could not be reimbursed for the cost of the caregiver.

From the testimony of both plaintiffs' witnesses and from Dr. Blagg, a Government witness who is a conceded expert in home dialysis treatment, it is clear that the HIC system of providing in-home dialysis is an excellent method for providing care of this kind. Now, I want to first turn to defendants' contention this Court does not have jurisdiction over this case.

I do have jurisdiction. Plaintiffs have no adequate remedy at law available to them. Defendants argued that the plaintiffs should exhaust their administrative remedies under the Medicare appeals process. However, such a claim could not be brought, at least until many months after January 1, 1989, when the new rates of reimbursement go into effect. No, I guess it's February 1, 1989, when the [741] new rates of reimbursement go into effect.

It is clear from the testimony that requiring plaintiff, HIC, to endure an administrative proceeding result in the irreversible demise of HIC's home dialysis service. That's clear from the testimony of the plaintiff's Chief Executive Officer, Dr. Jacob, whose testimony I credit on this point. Therefore, to require that he exhaust administrative remedies after he is out of business would render the case moot and any ultimate judgment would be purely a purit [*sic*] victory.

Further, going the administrative route require all of HIC's patients to find alternate sources of treatment. Such relocation would be traumatic, and in some instances, life threatening. So that as I said before in one of the preliminary hearings, if there ever was a case crying out for the Court to intercede at this time so that all the issues can be determined, this is such a case.

Moreover, the challenge raised by plaintiff is against the method by which Method 2 reimbursement level was determined, as well as a challenge to the determination itself. Under Bowen versus Michigan Academy, this Court clearly has jurisdiction to resolve this matter.

This lawsuit arose out of a series of events which led to a reduction in allowable reimbursement for in-home kidney hemodialysis under Method 2. Indeed, what has [742] happened in this case is that defendants have, in fact, been denied the use of Method 2—the defendants have, in fact, in this case denied the plaintiffs the ability to use Method 2 for reimbursement.

Plaintiffs claim that a transmittal letter No.—Transmittal 1237, sent out by the Home Care Financing Administration in February of 1988 to all its Medicare Part B carriers amounted to a change in a substantive legal standard. If so, such an action requires notice in the Federal Register and a comment period before final promulgation. In part defendants' ability to issue Transmittal 1237 was based on an early action by the Department of Health and Human Services.

In a 1986 amendment to the Medicare Act, Congress directed that the Secretary of HHS to issue regulations

controlling the discretion of carriers in establishing special reasonable charge limits for a particular item. At issue here are standards of inherent reasonableness. The Home Care Financing Administration did publish proposed rules for notice and comment as required by law. However, on August 11, 1987, when the final rules were proposed, a change to the initial proposal had been made. The final rules applied not only to the Home Care Financing Administration, but to Medicare Part B carriers as well.

Plaintiffs argue this was not merely an insubstantial change to the regulations. Rather plaintiffs urged [743] this Court to find that there is a substantial difference between inherent reasonableness criteria that would be applied by the Home Care Financing Administration and identical standards applied by carriers. Therefore, plaintiffs again believe that notice and comment proceedings were required.

Further, the plaintiffs view the actual method that Blue Cross-Blue Shield of Florida followed in setting its new levels of reimbursement was arbitrary and capricious and contrary to law.

Finally, plaintiffs argue that the actions of the defendants taken as a whole violate the Medicare statute. There is also due process claim in the complaint. Now, in determining whether a preliminary injunction is to issue, I have really four issues to look at.

One, has the petitioner made a strong showing that is likely to prevail on the merits of its appeal?

Two, has the petitioner shown without such relief he will be irreparably injured?

Three, would the issuance of a stay substantially harm other parties interests in the proceeding?

Four, where lies the public interest?

Now, let me first turn to the success on the merits issue. Plaintiff has demonstrated to the satisfaction of the Court that Transmittal 1237 was, in fact, a directive that [744] resulted in doing away with Method 2 reim-

bursement, and, in effect, provides that reimbursement for in-home dialysis will solely be on a Method 1 basis, that is the composite rate basis.

The witness produced by Blue Cross-Blue Shield made clear that Blue Cross-Blue Shield understood what was expected of the carrier when it received the transmittal in question. That is they were to cut the rate, the prevailing rate. After a perfunctory study, they, indeed, did cut the rate, and went to the Method 1 system of reimbursement.

I find it almost inconceivable that Blue Cross-Blue Shield of Florida would have determined on its own to set the rate of reimbursement under Method 2 at a level identical to the national reimbursement rate under Method 1 unless they believed that was the instructions that they were receiving from Washington. Now, again, this is a preliminary determination. In the final determination, I might change that finding. However, from the testimony I heard here today, I come to the conclusion from everything I heard, from all the documents that these were instructions coming from Washington.

In addition, Dr. Jacob testified and produced letters which indicated that the Home Care Finance Administration intended to eliminate Method 2 payments for HIC's home hemodialysis program. This evidence includes a document which [745] clearly shows that before Florida Blue Cross had reached a decision on the level of reimbursement it intended to provide under Method 2, it had already received a draft letter from HCFA demonstrating how to notify beneficiaries of the change in reimbursement rates to Method 1, and discussing the effects of such a change. This draft letter was incorporated in substantial part in the letter which Florida Blue Cross ultimately sent to the beneficiaries.

Dr. Jacob also recounted a conversation with one Mr. Robert Streimer, a former high official of HCFA, who stated that HCFA was going to put HIC out of business. Now, that's the only testimony I have on that point. The

testimony has not been contradicted, and we have not had an opportunty to hear from Mr. Streimer, and I'm sure that his deposition or his testimony will be provided in the final judgment, but based on the record I have now, that's in the record.

In addition on Ocotber 21, 1987, Mr. Streimer wrote a letter to Dr. Jacob which stated that henceforth all HIC reimbursement would be on the basis of Method 1. While that decision was ultimately suspended, it certainly showed the state of mind of Mr. Streimer, who is a top—who was a high official of the HCFA operation.

I believe that the plaintiffs have sufficiently demonstrated that Transmittal 1237 was, in fact, a directive from HCFA to do away with Method 2, and require all [746] reimbursements for these services under Method 1. This was not simply a reduction in the rate, but a substantive change in policy, namely the elimination of Method 2, which in my view could not be done without Congressional action or at the minimum, if possible, going through the notice and comment process as required by the Administrative Procedure Act. I leave that issue to the final determination. I don't even know whether notice and comment would be adequate, but that wasn't even done in this case.

Further, I find that HCFA's change in its proposed rule, the change being that it allowed the carriers to make inherent reasonableness determinations was a substantial change. It was a substantive change. Clearly when Congress enacted the legislation directing that the Secretary of HHS promulgate such regulations, the intent was to exert closer control over carriers. Therefore, an amendment to the proposed regulation which would allow for unilateral actions by the carriers could not be anything but a substantive and substantial change. Therefore, a new notice and opportunity for comment proceedings, in my view, would be required.

Next, it seems equally clear that the very process Blue Cross-Blue Shield followed in setting its rates was arbi-

trary and capricious. Although Blue Cross's witness attempted to explain the procedure Blue Cross followed, upon further examination it became clear that ultimately Blue Cross [747] simply put the Method 1 rate into place.

Certainly if a proper Method 2 analysis had been done, the reimbursement would have been greater than was enacted. And this point was conceded by the representative from Blue Cross-Blue Shield who testified that if he had had all the facts that he could conceivably have justified a fee of perhaps as much as $600 more than had been allowed under the fee that Florida Blue Cross-Blue Shield adopted.

Indeed, Dr. Blagg, the Government's own witness and an expert of unquestioned qualifications stated that plaintiffs' costs were by and large reasonable.

Now, I'm not very happy with Dr. Jacob in his refusing to turn over his own cost data. He could have perhaps helped his own case if he had acceded to the request of Blue Cross-Blue Shield, and if the witness from Blue Cross-Blue Shield was candid in his response to my question, it could have resulted in a higher return to the plaintiff, HIC.

I do, however, understand the reason that Dr. Jacob refused to turn over that information. He stated that it would have been futile to do so, because of the fact that he thought that the die had been cast and that it was a pre-ordained conclusion that the attempt was to force his organization out of business.

Now, that's his state of mind. Whether he is correct or not, we'll have to leave to another day. And while [748] I can't say his fears were totally unjustified, I do not want to condone what he did, because it is only in that way, if he had, in effect, acceded to the request of Blue Cross-Blue Shield that we could have, in fact, teed up the issue for final decision.

At this point, it is clear to me, at least on a preliminary basis that HCFA sought to eliminate payment for home hemodialysis under a separate Method 2 rate. HCFA

attempted to have all home care reimbursed under Method 1. Clearly in doing this, there is the real possibility that HCFA was attempting to do away with Method 2 rate and this it is conceded cannot be done under the Medicare statute.

So again, I'm saying that's another issue that must await determination on the final hearing. But clearly, if it was an attempt by HCFA to do away with Method 2 form of reimbursement, a Congressional enactment was required.

Congress intended for there to be two separate and distinct methods for payment. Method 1 was to be a composite rate. Method 2 was to be a reasonable cost rate. Since there is this strong possibility that HCFA has attempted to make all payments under the composite rate, that would be contrary to law.

Indeed, HCFA sought such action from Congress recently, but Congress declined to act. From this inaction I conclude that Congress chose to preserve the Method 2 form [749] of payment.

Of course, as any other citizen, and knowing that Congress and the Administration has the responsibility to control Government costs, that I am concerned about the issues of costs that have so far been raised in this case. Clearly those who oversee this program should establish solid criteria upon which determination of reasonableness are to be made. That is, in fact, what Congress directed, and what, by and large, the Administration is attempting to carry out.

However, those charged with the duty of oversight cannot in their—strike the cannot—in their zeal to carry out this directive cannot simply take actions which are contrary to certain competing requirements of the law and specific Congressional enactments.

So far—strike that.

HCFA must also take into account the fact that we have people in need of home dialysis services. From what I heard during the past three days, this is not a disease

of choice, and it is clear to me so far, and obviously my opinion can change when I hear more, but up to this point, it is clear to me that the plaintiff, HIC, has delivered an important and necessary service on a first rate basis. It has filled a void in the delivery of home care and from the testimony I've heard from certain of the beneficiary witnesses, [750] it has made their quality of life much better.

For all these reasons, I find that the plaintiffs have shown substantial likelihood of success on the merits. I stress that this is only a preliminary determination and the final determination must await the final hearing.

Now I turn to irreparable harm. Plaintiffs certainly have demonstrated that irreparable harm would result from not issuing a preliminary injunction. Dr. Jacob has testified that HIC would not survive unless it is able to continue its present operation. I believe his testimony. There is nothing I have seen that would indicate that he would be able to provide a service that he is now able to provide at $3,100 a month at the rate of $1,650 a month. And there has been nothing in the record to the contrary.

But once the new rates go into effect, not only will HIC's reimbursement be reduced, but it will also start losing its staff. As a result, HIC will be forced to transfer its patients to other providers of hemodialysis treatment, predominantly in-clinic treatment.

Now, in this action we have an interest that is really more paramount than HIC, and that is the other plaintiffs who are receiving this very necessary and vital service. The witnesses that testified were extremely compelling. They made it clear that they would be dramatically harmed by the failure of this Court to issue this injunction.

[751] One witness testified that his son, a diabetic, who suffers from numerous other ailments, including end stage renal disease, risks his life traveling to a clinic. Another witness, the mother of a young 10 year old child, said that since she's been receiving this service from the plain-

tiff, HIC, that her child has been able to lead a somewhat normal life. That the child is able to have friends, be able to go to school and she is free from having to travel two and half hours every third day to get this treatment.

There was another witness that testified that he lives in a small town where the dialysis clinic was providing only subpar service. And the only way that he could obtain the kind of care that was necessary to sustain his life was through the services provided by HIC.

Every witness indicated that their health and well being would be harmed if the plaintiff, HIC, were to cease operation. You got to remember that the kind of disease we're talking about and the kind of treatment we're talking about is required to sustain life. These people, if they can't get dialysis treatment, die. They can't live without this treatment. And I guess that was really the basis of the testimony of one witness who indicated that he was having such a difficult time being treated at a clinic where he was being treated in an impersonal and sometimes inhumane way, that he said that if he were unable to obtain [752] adequate in-home dialysis treatment, he would pull his own plug and let himself pass to another life.

There is no doubt, therefore, that plaintiffs have demonstrated irreparable harm. Indeed, I don't know how it could help anybody to change the system now pending the final determination of the issues.

Now, harm to other parties. Well, I don't know of any harm to other parties, other than the fact that there may well be some additional costs that will have to be paid out during the time that it takes for this case to be litigated and tried, but I don't think the costs that are going to be incurred in treating—that are going to be incurred is going to harm this great nation of ours. I don't think they have to balance the budget on the back of these 1,000 patients who, again, as I say, are not in this because of choice, but are in it strictly to stay alive.

Now, the public interest element, I turn to next. In my view, it is certainly in the public interest to maintain the status quo pending the ultimate determination of the very critical issues that have been raised. Now, that's not to say that there can be no oversight of the plaintiff, and the—plaintiff, HIC, and the plaintiff can charge whatever he wants, whatever it wants.

But I do think that unless Congress changes the Method 2 payment, that HCFA will have to deal with Method 2 on [753] the merits and not attempt to deal with it in the clumsy way that it has done so far. And I say that as advisedly as I can, but as I start going through some of these records that have been presented in this case, which shows the five or six ways that they have tried to deal with this problem, it almost reminds me of that former actor who played a person called Inspector Cluseu who just couldn't get the act together.

Now, again, there are certainly ways of dealing with the problem that HCFA believes exist, but certainly they can deal with them better than they have. Certainly it is not going to hurt them to have to put notice and comment out. Certainly it's not going to hurt them to establish criteria for who should be able to obtain home—in-home dialysis services. These can all be done, and, indeed, from the last witness who testified who said that they are planning to have a comment period. Why we can't wait until that process is over so we can—so that the proper decisions can be made is beyond me.

But I do want to emphasize that I have not made any final determination, and the only reason I've made these preliminary determinations is because I've been forced to do so, because of the inability of the parties to work out a bridge order, and I should say again these determinations are solely for the purpose of making my determination on plaintiffs [754] motion for a preliminary injunction. And accordingly, I've kept everybody in suspense up until now, I've decided to issue a preliminary injunction and will enjoin the defendants pending the final determination of this case, and I will issue an

order tomorrow. Oh, I can't issue it tomorrow. I've got to issue it tonight because I'm not going to be here.

Madam Clerk, will you enter it tomorrow. If we still have a secretary, I will issue it.

MR. LEPLEY: Your Honor, a couple of final points.

THE COURT: Surely.

MR. LEPLEY: First of all, I don't know the scope of your order, but the Government would ask that it enjoin HIC from enrolling new patients, and certainly the patients that they have is fine, but they shouldn't grow.

Secondly, it should be limited to the Florida carrier and third, only to home hemodialysis, not CAPD or CCPD.

THE COURT: You'll get my order. I'm going to make it—what I'm doing is very simply I'm going to maintain the status quo. I can't deal with this now.

Now, if you want to sit down with Dr. Jacob and try to work out some reduction in the fees, I'm going to retain jurisdiction so you can come back. That would be the way I would proceed, and I think that the doctor had indicated that he's willing to do it, and that's the way I'd [755] proceed. But you see what happens, once you limit him, then he's going to die. A business like this can't exist if it is limited. He's got money invested—I mean I know from my business background that he can't—he's opened—I'm sure he's opened a new facility somewhere where he needs certain patients to take care of the overhead.

Now, I think we could, that you may well want to come up and show some sort of a generic—to limit some kind of a generic kind of expansion might be appropriate. In other words, that he shouldn't start opening new facilities.

MR. LEPLEY: Well, that's just not to enroll new patients.

THE COURT: No, new patients, you see, you can't do that because he's got overhead he's got to deal with. But if you can come up with something, I would suggest

you talk to him. I will issue this order and then I will issue an amendment if need be.

Can you come up with something along those lines, where—

MR. LEWIN: This is the first I've heard of any such suggestion, Your Honor. He's trying to do exactly what Mr. Streimer did in that letter in that infamous Pearl Harbor day.

MR. LEPLEY: Your Honor, I—

THE COURT: It's late, Mr.—

[756] MR. LEWIN: That's what he's doing right now.

THE COURT: Can I tell you something?

MR. LEPLEY: Your Honor—

THE COURT: Excuse me. Mr. Lewin, it's late, and I don't need any personal attacks. I didn't find that he did anything that was in any way inappropriate and I think he's doing what is appropriate. There is no need for personal attack. It's 6:45.

MR. LEPLEY: Your Honor, the final two things, and I don't want to try and cause patience, but the Government would both move for a stay pending appeal and also for a bond to be posted as is required.

THE COURT: Well, we'll have to deal with the bond at some point, but the stay, in effect, gives you the win, and that you can't do. That's what this thing is all about and a stay would be so wrong to do in this case that I can't imagine anything that could be worse.

Appropriate bond, I think you've got a—

MR. LEWIN: Well, a bond, I think, at least to me, strikes me as the same thing as his escrow proposal that he's been proposing all along. Obviously if we're going to go out and get a bond, that means we've got to pay a bonding company.

THE COURT: Well, there is—I'll have a hearing if you want, but I don't think that you can't come up with a [757] bond of a certain amount of money. It doesn't have to bond the whole deal.

MR. LEPLEY: All we ask is the difference between—

THE COURT: Well, let me say this to you.

MR. LEWIN: That's the same as his escrow. That's exactly what he—you know, the very first thing he said to us, put the money in escrow. If we're going to put up a bond—

THE COURT: I think this case is a little different and I'll tell you why. I don't think there is money that is going to come back, because any decision that I make is going to be a prospective decision. It's going to be a prospective—in other words, if I determine that he is wrong, it's going to be prospective. He's entitled to that, I think. Unless you can convince me I'm wrong, and I'll accept briefs on that, I don't think this is the case for a bond, although I'll hear you.

I will issue my opinion—I mean my order tomorrow. My opinion is in the record. You can arrange with the reporter to get my opinion. Those were my findings of fact and conclusions of law. My order will be issued tomorrow. If there is anything further you want to take up and brief, I will be glad to have it.

MR. LEPLEY: I was just going to say, thank you, Your Honor.

[758] THE COURT: I also would say to talk to Mr. Lewin, who I hope will be reasonable.

MR. LEWIN: I think I'm always reasonable.

THE COURT: Thank you. It's been a trying case.

(Proceedings concluded at 6:50 p.m.)

APPENDIX E

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 91-5073

NATIONAL KIDNEY PATIENTS ASSOCIATION, *et al.*

v.

OTIS R. BOWEN, Dr. Secretary, Department of Health and Human Services,
Appellants

BEFORE: Ruth B. Ginsburg, Williams and Sentelle, Circuit Judges

ORDER

[Filed June 1, 1992]

Upon consideration of appellees' petition for rehearing, filed April 27, 1992, it is

ORDERED, by the Court, that the petition is denied.

Per Curiam
FOR THE COURT:

CONSTANCE L. DUPRE
Clerk

By: /s/ Robert A. Bonner
ROBERT A. BONNER
Deputy Clerk

No. 92-569

In the Supreme Court of the United States

OCTOBER TERM, 1992

NATIONAL KIDNEY PATIENTS ASSOCIATION, ET AL., PETITIONERS

v.

LOUIS W. SULLIVAN, SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

BRIEF FOR THE RESPONDENTS IN OPPOSITION

KENNETH W. STARR
Solicitor General

STUART M. GERSON
Assistant Attorney General

ANTHONY J. STEINMEYER
ROBERT M. LOEB
Attorneys

Department of Justice
Washington, D.C. 20530
(202) 514-2217

QUESTION PRESENTED

Whether a Medicare claimant must present a claim for payment before seeking judicial review of a Medicare policy or regulation governing the method of determining the amount or the allowance of Medicare benefits.

TABLE OF CONTENTS

	Page
Opinions below	1
Jurisdiction	1
Statement	2
Argument	7
Conclusion	15

TABLE OF AUTHORITIES

Cases:

Abbey v. *Sullivan*, No. 92-6055 (2d Cir. Sept. 28, 1992)	11, 12, 13
Bodimetric Health Services, Inc. v. *Aetna Life & Casualty*, 903 F.2d 480 (7th Cir.), cert. denied, 111 S. Ct. 579 (1990)	14, 15
Bowen v. *Michigan Academy of Family Physicians*, 476 U.S. 667 (1986)	6, 9, 10
Bowen v. *Yuckert*, 482 U.S. 137 (1987)	11
Heckler v. *Ringer*, 466 U.S. 602 (1984)	5, 8, 9
McCuin v. *Secretary of HHS*, 817 F.2d 161 (1st Cir. 1987)	14
McNary v. *Haitian Refugee Center, Inc.*, 111 S. Ct. 888 (1991)	10
Mathews v. *Eldridge*, 424 U.S. 319 (1976)	8
National Kidney Patients Ass'n v. *Sullivan*, 958 F.2d 1127 (D.C. Cir. 1992)	13
Roen v. *Sullivan*, 764 F. Supp. 555 (D. Minn. 1991)	11, 12
United States v. *Erika, Inc.*, 456 U.S. 201 (1982)	9
Weinberger v. *Salfi*, 422 U.S. 749 (1975)	8, 11
Westchester Management Corp. v. *HHS*, 948 F.2d 279 (6th Cir. 1991), cert. denied, 112 S. Ct. 1936 (1992)	11, 14

Constitution, statutes and regulation: Page

U.S. Const.:
Art. I, § 7, Cl. 2 (Pocket Veto Clause) 12
Amend. V (Due Process Clause) 9
Administrative Procedure Act:
5 U.S.C. 553 4
5 U.S.C. 703 12
Health Insurance for the Aged Act (Medicare Act), Pub. L. No. 89-97, § 102(a), 79 Stat. 291 2
Omnibus Budget Reconciliation Act of 1986, Pub. L. No. 99-509, 100 Stat. 1874:
§ 9341, 100 Stat. 2037 10
§ 9341(b), 100 Stat. 2038 13
Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, § 6203(b)(1), 103 Stat. 2235 5
Social Security Act:
Tit. II, 42 U.S.C. 301 *et seq.*:
42 U.S.C. 405(g) 6, 8
42 U.S.C. 405(h) 6, 8, 9
Tit. XVIII, 42 U.S.C. 1395 *et seq.*:
42 U.S.C. 1395 *et seq.* 2
42 U.S.C. 1395c-1395i-4 (1988 & Supp. II 1990) 2
42 U.S.C. 1395j-11395w-4 (1988 & Supp. II 1990) ... 2
42 U.S.C. 1395u(b)(3) 3
42 U.S.C. 1395u(b)(8)(A) 3
42 U.S.C. 139ff 6, 9, 14
42 U.S.C. 1395ff(a)-(b) (1982 & Supp. II 1984) 9
42 U.S.C. 1395ff(b) 7
42 U.S.C. 1395ff(b)(1) 11
42 U.S.C. 1395ff(b)(1)(C) 9, 10
42 U.S.C. 1395ff(b)(2) 14
42 U.S.C. 1395ii 6, 7
42 U.S.C. 1395rr(b)(1)(A) 2
42 U.S.C. 1395rr(b)(1)(B) 2
42 U.S.C. 1395rr(b)(7) 2
42 U.S.C. 1395rr(b)(8) 2
28 U.S.C. 1331 ..... 6, 8, 10, 12
42 C.F.R. 405.502(g) 3, 4

Miscellaneous—Continued: Page

138 Cong. Rec.:
p. H12,379 (daily ed. Oct. 5, 1992) 12
p. S18,262 (daily ed. Oct. 22, 1992) 12
H.R. 11, 102d Cong., 2d Sess. (1992) 12
H.R. Rep. No. 727, 99th Cong., 2d Sess. (1986) 12
28 Weekly Comp. Pres. Doc. No. 45 (1992) 12

In the Supreme Court of the United States

OCTOBER TERM, 1992

No. 92-569

NATIONAL KIDNEY PATIENTS ASSOCIATION, ET AL., PETITIONERS

v.

LOUIS W. SULLIVAN, SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

BRIEF FOR THE RESPONDENTS IN OPPOSITION

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-22a) is reported at 958 F.2d 1127. The opinion of the district court (Pet. App. 23a-35a) is reported at 754 F. Supp. 900.

JURISDICTION

The judgment of the court of appeals was entered on March 13, 1992. A petition for rehearing was denied on June 1, 1992. Pet. App. 59a. On July 29, 1992, the Chief Justice extended the time for filing a petition for a writ of certiorari to and including September 29, 1992. The petition was filed on September 29, 1992. The jurisdic-

tion of this Court is invoked pursuant to 28 U.S.C. 1254(1).

STATEMENT

1. Title XVIII of the Social Security Act, as added by the Health Insurance for the Aged Act, Pub. L. No. 89-97, § 102(a), 79 Stat. 291—popularly known as the Medicare Act—establishes a health insurance program for eligible aged and disabled persons. 42 U.S.C. 1395 *et seq.* The Medicare Program is administered by the Secretary of Health and Human Services (HHS) through the Health Care Financing Administration (HCFA). The Act is divided into two parts. Part A of the Act authorizes payment for hospital and related post-hospital services. 42 U.S.C. 1395c to 1395i-4 (1988 & Supp. II 1990). Part B of the Act authorizes payment for supplementary medical services. 42 U.S.C. 1395j to 1395w-4 (1988 & Supp. II 1990). This case involves reimbursement under Part B for home kidney dialysis equipment and supplies.

There are two methods of obtaining reimbursement under Part B for home dialysis equipment and supplies. Under Method I, certified facilities are reimbursed based on a formula established by the Secretary. 42 U.S.C. 1395rr(b)(1)(A) and (b)(7). Under Method II, entities that are not certified facilities are reimbursed on a "reasonable charge" basis. 42 U.S.C. 1395u(b)(3), 1395rr (b)(1)(B) and (b)(8). See also Pet. App. 2a-3a. The "reasonable charge" generally is the lowest of (1) the supplier's actual charge, (2) its customary charge, or (3) the prevailing charge in the area. 42 U.S.C. 1395u(b)(3). In addition, Congress has directed the Secretary to identify by regulation instances in which the standard criteria would lead to a charge that is "grossly excessive" (or "grossly deficient"), such that the charge is not

"inherently reasonable." 42 U.S.C. 1395u(b)(8)(A). The Secretary has implemented this provision through a regulation that authorizes HCFA or the carrier to determine that a charge is inherently unreasonable and to prescribe a substitute rate. 42 C.F.R. 405.502(g). Method II affords patients who self-dialyze at home the option of contracting directly with a supplier of home dialysis equipment and supplies, instead of receiving home dialysis equipment and supplies from a certified facility.

2. In 1988, petitioner Home Intensive Care, Inc. (HIC), was the largest supplier of home dialysis equipment under Method II in Florida. HIC supplied dialysis equipment and supplies to approximately 1,000 patients at a rate of $3,100 per month. Although Method II payments cover only dialysis equipment and supplies, HIC provided its clients with "free" staff assistants to aid the patients during home hemodialysis sessions. C.A. App. 18, 30-31.

On July 12, 1988, Blue Cross and Blue Shield of Florida (Blue Cross), the local Medicare Part B carrier, issued a notice proposing to reduce the maximum monthly allowance under Method II for home dialysis supplies and equipment from $3,100 to $1,625. Blue Cross solicited comments on the proposed reduction, surveyed dialysis facilities, and requested cost information from dialysis equipment suppliers. Pet. App. 4a; C.A. App. 55-57.

Upon completion of its evaluation of the comments and cost information, Blue Cross determined that the $3,100 charge was unreasonable and that the new monthly payment maximum would become effective on January 1, 1989. C.A. App. 55, 63. In its letter to suppliers, Blue Cross noted that HIC had refused to reveal its acquisition and operating costs. C.A. App. 57. Based on the cost information available from other suppliers,

however, Blue Cross determined that a charge of $3,100 per patient per month was more than three times the suppliers' cost and was "grossly excessive." C.A. App. 56-57. Blue Cross explained that more than 75% of all home dialysis equipment and supplies were provided by Method I providers, and that there was no reason to believe that Method I providers (who charged only $1,625 per month for such services) had lower costs than Method II suppliers. C.A. App. 56-59, 61-62. Blue Cross rejected the argument that the provision of "free" assistants justified the higher Method II rate, explaining that the cost of such assistants is not reimbursable under the Medicare Act. C.A. App. 61.

3. Petitioners—HIC, a renal dialysis patients' group, and ten individual renal dialysis patients who received dialysis equipment from HIC—failed to present a claim for payment under the reduced rate. If petitioners had done so, they could have obtained administrative review of Blue Cross's rate reduction and judicial review of the Secretary's final determination if their claims for increased reimbursement were denied. Instead of presenting a claim, petitioners filed an action directly in the district court seeking to enjoin the rate reduction. Pet. App. 4a. Petitioners' complaint alleged (1) that the general regulation that authorized Blue Cross to find HIC's charge "inherently unreasonable" (42 C.F.R. 405.502(g)) was not properly promulgated; (2) that a transmittal letter issued by the HCFA urging carriers to examine the reasonableness of Part B dialysis equipment rates violated the Medicare Act and was a substantive rule requiring notice-and-comment rulemaking under the Administrative Procedure Act (APA), 5 U.S.C. 553; and (3) that the carrier's decision to reduce the rate was "arbitrary and capricious." Pet. App. 5a.

In December 1988, the district court issued a preliminary injunction, enjoining the Department of Health and Human Services from reducing the rate paid to HIC. Pet. App. 5a.

4. The government appealed the district court's order, arguing, *inter alia*, that the district court lacked jurisdiction because petitioners failed to present a claim for payment covered by the challenged rate reduction and failed to exhaust their administrative remedies. While the case was on appeal, "Congress commanded what the district court had enjoined." Pet. App. 5a. Section 6203(b)(1) of the Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, 103 Stat. 2235, amended 42 U.S.C. 1395rr(b)(7) to cap Method II home dialysis payments at the Method I level. Pet. App. 5a. As a result of the new legislation, the district court modified its injunction to allow HHS to reduce future payments to HIC. *Ibid.* Thereafter, the court of appeals dismissed the government's appeal from the preliminary injunction as moot, vacated the district court's order, and remanded for consideration of whether the government could recoup overpayments made pursuant to the injunction. Pet. App. 36a-42a.

5. On remand, the district court ruled that HHS could not recover under the injunction bond or recoup any of the payments made pursuant to the injunction. The court concluded that its prior ruling was correct in all respects. The court further held that, even if its prior ruling was in error, it would be inequitable to require HIC to repay any of the money paid to it under the preliminary injunction. Pet. App. 5a-6a, 27a-35a.

6. The court of appeals reversed. Pet. App. 6a-22a. It held that the district court lacked jurisdiction to enter the injunction. In *Heckler* v. *Ringer*, 466 U.S. 602 (1984),

this Court construed the judicial review provisions of the Medicare Act, 42 U.S.C. 1395ff (incorporating 42 U.S.C. 405(g)) and 42 U.S.C. 1395ii (incorporating 42 U.S.C. 405(h)), to require presentment of a claim to the agency ("an absolute prerequisite") and exhaustion of the administrative process ("a prerequisite that may be excused only under rather limited conditions") before a court may assert jurisdiction over claims arising under *Part A* of the Medicare Act. Pet. App. 6a-11a. In 1986, Congress amended those judicial review provisions—which had applied only to Part A—to include Part B claims. Pet. App. 8a-9a, 12a. In light of the 1986 amendment, the court of appeals found it "inescapable that the same rule[s] must [now] govern parts A and B." Pet. App. 12a. Accordingly, the court held that a district court may not assert jurisdiction over Part B claims where, as here, the claimant has failed to present a claim to the agency for payment under the policy or regulation at issue. Pet. App. 10a-13a.

a. The court of appeals distinguished this Court's decision in *Bowen* v. *Michigan Academy of Family Physicians*, 476 U.S. 667 (1986), which allowed judicial review of Part B methodology challenges in a suit based on the general judicial review provisions of the APA and 28 U.S.C. 1331. The court of appeals explained that *Michigan Academy*, which was decided before the 1986 amendment to the judicial review provisions, rested on the presumption that Congress did not intend to preclude *all* judicial review of serious statutory and constitutional questions arising under Part B. Pet. App. 11a-12a. The court of appeals concluded that *Michigan Academy* no longer governs Part B claims, because Congress has now provided a route for judicial review under 42 U.S.C. 405(g) after presentment and exhaustion

of the administrative process. Pet. App. 12a-13a. Under the 1986 amendment, "[P]art B claims will not go unreviewed; review simply awaits *initial* administrative determination in a concrete setting." Pet. App. 13a

b. The court of appeals also held that HHS, as a defendant injured by a wrongfully issued preliminary injunction, is presumptively entitled to obtain recovery from the injunction bond. Pet. App. 15a-17a. The court found that none of the equitable arguments raised by petitioners were sufficient to overcome that presumption. Pet. App. at 17a-18a. The court further ruled that HHS has the right to seek restitution in excess of the amount of the bond through the usual Medicare procedures for seeking recoupment of overpayments. *Id.* at 20a-22a. The court added that when HHS recoupment procedures "have run their full course, HIC may, if not content with the outcome, seek judicial relief in an appropriate forum." Pet. App. at 22a.[1]

ARGUMENT

The decision of the court of appeals is correct and is consistent with the decisions of this Court and the only other court of appeals to have decided the issue. Accordingly, further review is not warranted.

1. The court of appeals correctly held that petitioners were required to present a claim for Medicare benefits to the Secretary as a prerequisite to seeking judicial review.

a. The Medicare Act's judicial review provisions, 42 U.S.C. 1395ff(b), 1395ii, incorporate by reference the judicial review provisions of Title II of the Social Security

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[1] Petitioners do not seek review of these rulings by the court of appeals regarding HHS's rights to recovery.

Act, 42 U.S.C. 405(g), 405(h). In *Heckler* v. *Ringer*, 466 U.S. 602 (1984), the Court held that a claimant asserting claims arising under Part A of the Medicare Act must satisfy the same exhaustion requirement applicable under Section 405(g). The Court explained that this exhaustion requirement has two components: (1) a "nonwaivable" requirement that a claim for benefits must be presented to the Secretary; and (2) a "waivable" requirement that the claimant must have fully pursued the administrative review process. 466 U.S. at 617. See also *Mathews* v. *Eldridge*, 424 U.S. 319, 328 (1976); *Weinberger* v. *Salfi*, 422 U.S. 749, 763-765 (1975).

Mr. Ringer challenged the Secretary's policy concerning Part A Medicare insurance coverage of a surgical procedure known as a bilateral carotid body resection (BCBR). This Court held that because he had not filed a claim for reimbursement, he was barred from seeking judicial review under either the Medicare Act or the general grant of federal jurisdiction in 28 U.S.C. 1331. 466 U.S. at 621-622. The Court explained that because "Ringer has not given the Secretary an opportunity to rule on a concrete claim for reimbursement, he has not satisfied the nonwaivable exhaustion requirement of § 405(g)." *Id.* at 622.

b. Petitioners incorrectly assert (Pet. 15) that they need not present a claim for payment to the Secretary before seeking judicial review because *Ringer* only dealt with "amount determinations." Petitioners contend (Pet. 13-15) that parties challenging the Secretary's polices or methodologies may proceed directly to court without even filing a claim with the Secretary. Petitioners' contention is inconsistent with *Ringer*, which involved "methodology" challenges similar to those at issue in this case. Mr. Ringer sought to "invalidate the Secre-

tary's rule" regarding coverage of BCBR surgery, contending that the Secretary's instructions regarding reimbursement violated the Due Process Clause, the Administrative Procedure Act (APA), and the Medicare Act. 466 U.S. at 610, 623 n.13. The Court explained that Ringer was challenging the policy so that he could establish the right to payment on a claim at a later date. 466 U.S. at 621-626. This Court concluded that it made no difference whether the suit raised procedural objections or substantive challenges to the Secretary's regulations; Ringer could not seek judicial review without presenting a claim for payment. *Ibid.*[2]

c. This case involves claims under Part B of the Medicare Act. Prior to 1986, the judicial review provisions discussed in *Ringer* applied to Part A claims, but not to Part B claims. Indeed, the Medicare Act did not expressly furnish Part B claimants with *any* avenue for seeking judicial review, see 42 U.S.C. 1395ff(a)-(b) (1982 & Supp. II 1984). For that reason, this Court had held in *United States* v. *Erika, Inc.*, 456 U.S. 201, 210 (1982), that in light of the carefully drawn provisions of 42 U.S.C. 1395ff permitting judicial review of benefit amount determinations under Part A but not Part B, review of such determinations under Part B was implicitly precluded. Thereafter, in *Bowen* v. *Michigan Academy of Family Physicians*, 476 U.S. 667 (1986), this Court declined to read the Medicare Act as precluding all judicial review for Part B claimants. 476 U.S. at 678-681. Accordingly,

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[2] Petitioners argue (Pet. 14-15) that, because 42 U.S.C. 1395ff(b)(1)(C) applies to benefit "amount" determinations, it is only judicial review of such determinations that is impliedly precluded by 42 U.S.C. 1395ff. But petitioners overlook 42 U.S.C. 405(h), which expressly bars this suit, quite apart from any implied preclusion in 42 U.S.C. 1395ff.

the Court held that a party challenging the Secretary's methods and procedures relating to Part B claims could seek judicial review pursuant to the general judicial review provisions of the APA, with jurisdiction resting on 28 U.S.C. 1331.

Underpinning the Court's holding in *Michigan Academy* was "the strong presumption that Congress intends judicial review of administrative action." 476 U.S. at 670. Absent a clear Congressional statement to the contrary, the Court refused to read the Act to preclude all judicial review of challenges to directives and other actions taken by the Secretary, as distinguished from amount determinations by carriers. *Id.* at 680. As this Court recently explained in *McNary* v. *Haitian Refugee Center, Inc.*, 111 S. Ct. 888 (1991):

> Inherent in our analysis [in *Michigan Academy*] was the concern that absent such a construction of the judicial review provisions of the Medicare statute, there would be "no [judicial] review at all of substantial statutory and constitutional challenges to the Secretary's administration of Part B of the Medicare program."

111 S. Ct. at 899 (quoting *Michigan Academy*, 476 U.S. at 680).

d. Four months after this Court decided *Michigan Academy*, Congress amended 42 U.S.C. 1395ff(b)(1)(C) to authorize administrative *and judicial* review of Part B claims under the *identical* statutory scheme applicable to Part A claims. See Omnibus Budget Reconciliation Act of 1986, Pub. L. No. 99-509, § 9341, 100 Stat. 2037. Section 1395ff(b)(1)(C), as amended, now permits a claimant to obtain review of:

> the amount of benefits under part A *or part B* * * * [in] a hearing * * * by the Secretary * * * and to *judicial review* of the Secretary's final decision after such hearing as is provided in [42 U.S.C. 405(g)].

42 U.S.C. 1395ff(b)(1) (emphasis added). Thus, Part B claims are now subject to the same statutory review provisions as Part A claims. See Pet. App. 12a; *Abbey* v. *Sullivan*, No. 92-6055 (2d Cir. Sept. 28, 1992), slip op. 7081 ("Part B claims are now reviewed in the same manner as Part A claims."). As shown by this Court's decisions in *Ringer*, *supra*, *Bowen* v. *Yuckert*, 482 U.S. 137 (1987), and *Weinberger* v. *Salfi*, 422 U.S. at 756-767, challenges to regulations and even to the Act itself may and must be presented through this special statutory review procedure.

Because the statutory differences between Parts A and B that gave rise to the *Ringer/Michigan Academy* dichotomy have been eliminated, and because the fundamental premise of *Michigan Academy*'s analysis (the absence of any judicial review of Part B claims) is no longer applicable, the avenue for judicial review recognized in *Michigan Academy* is no longer available. See Pet. App. 12a-13a; *Abbey* v. *Sullivan*, slip op. 7080-7081; *Roen* v. *Sullivan*, 764 F. Supp. 555, 561 (D. Minn. 1991); see also *Westchester Management Corp.* v. *HHS*, 948 F.2d 279, 282 (6th Cir. 1991) ("the *Michigan Academy* exception applies only when there is no other avenue of judicial review"), cert. denied, 112 S. Ct. 1936 (1992). As the court of appeals here explained, under the 1986 amendment, "part B claims will not go unreviewed; review simply awaits *initial* administrative determination in a concrete setting." Pet. App. 13a.

e. Given that the same statutory review provisions now govern claims under Parts A and B, the court of ap-

peals correctly reached the "inescapable" conclusion that the same principles of judicial review "must [now] govern parts A and B." Pet. App. 12a. Accordingly, the court of appeals was plainly correct in holding that by bringing the Part B claims into the established Part A review framework, Congress intended to subject Part B claims to the same rules applicable to Part A claims under that existing framework. See H.R. Rep. No. 727, 99th Cong., 2d Sess. 95 (1986) (amendments establish "an appeals procedure under Part B that is modeled after that available under Part A"). See also *Abbey* v. *Sullivan*, slip op. 7078-7081 (holding that Part B claims are now governed by *Ringer*); *Roen* v. *Sullivan*, 764 F. Supp. 555, 561 (D. Minn. 1991) ("*Ringer*, which concerned Part A * * *, is now applicable to Part B claims as well."). Now, under both Part A and Part B, a party is at a minimum required to present a claim for benefits before seeking judicial review. As the APA itself makes clear, see 5 U.S.C. 703, a party may not circumvent this special statutory review procedure by resorting to the general judicial review provisions of the APA and the general jurisdictional grant in 28 U.S.C. 1331.[3]

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[3] We note that the jurisdictional issue addressed by the court of appeals has been the focus of recent legislative action. On October 22, 1992, Congress passed legislation that would have permitted direct judicial review of Part B challenges to regulations or Medicare instructions where no material issue of fact is in dispute. See H.R. 11, 102d Cong, 2d Sess. § 10210 (1992); see also 138 Cong. Rec. H12,379 (daily ed. Oct. 5, 1992) (setting out § 10210); 138 Cong. Rec. S18,262 (daily ed. Oct. 22, 1992). On November 5, 1992, that bill failed to become law under the "Pocket Veto" Clause, U.S. Const. Art. I, § 7, Cl. 2. 28 Weekly Comp. Pres. Doc. No. 45, at 2283 (1992).

2. a. The conflict in the courts of appeals alleged by petitioners is fictitious. As the court of appeals explained, this is the *first* case in which a court of appeals addressed the effect of the 1986 amendment on judicial review of Part B "methodology" claims. Pet. App. 15a. Since the court of appeals issued its decision in this case, one other court of appeals has addressed that issue. In *Abbey* v. *Sullivan*, *supra*, the Second Circuit fully agreed with the result and the reasoning in this case:

> [W]e agree with the only other Circuit to address this issue that "the special treatment of part B, based on the pre-October 1986 statutory differences, cannot survive the elimination of those differences." * * * Part B claims are now reviewed in the same manner as Part A claims so that the Social Security Act provides the exclusive authority for exercising jurisdiction over Part B disputes. See *Ringer*, 466 U.S. at 605.

Abbey, slip op. 7081 (quoting *National Kidney Patients Ass'n* v. *Sullivan*, 958 F.2d 1127, 1132 (D.C. Cir. 1992)).[4]

b. Petitioners also contend (Pet. 15) that the courts of appeals are in conflict over whether a *Part A* claimant raising a methodology challenge may seek judicial re-

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[4] Although petitioners contend (Pet. 15) that the decision in this case conflicts with other courts of appeals' decisions, none of the decisions cited by petitioners even discusses the 1986 amendments. Indeed, the cases cited by petitioners all involved pre-1987 Medicare claims. The 1986 amendment applies only to claims relating to services and items provided on or after *January 1, 1987*. See Omnibus Budget Reconciliation Act of 1986, Pub. L. No. 99-509, § 9341(b), 100 Stat. 2038. Decisions that did not concern (and therefore did not address) the 1986 amendment cannot establish a conflict concerning the jurisdictional rules applicable to Part B claims arising after the 1986 amendment.

view without filing a claim. As we explain above (pp. 8-9, *supra*), however, that issue was resolved in *Ringer*, which required presentment as a prerequisite for seeking judicial review of a methodology challenge. See also Pet. App. 10a, 12a-13a; *Westchester Management Corp.*, 948 F.2d at 282. In any event, the two decisions relied upon by petitioners do not conflict with the decision in this case.

In *McCuin* v. *Secretary of HHS*, 817 F.2d 161 (1st Cir. 1987), the type of claim at issue—a Part A claim involving less than $1,000—was not subject to any judicial review under 42 U.S.C. 1395ff. Thus *McCuin*, like *Michigan Academy*, raised the question whether Congress intended to preclude *all* judicial review of certain claims. As the Court held in *Michigan Academy*, there is a strong presumption in favor of judicial review of administrative action. Although we believe, contrary to the First Circuit in *McCuin*, that the amount-in-controversy requirement in 42 U.S.C. 1395ff(b)(2) is sufficient to overcome that presumption for claims involving less than the required amount, this case does not present that issue, because the amount-in-controversy requirement for invocation of the special statutory review procedure is met. As a result, in both *Ringer* and this case—in contrast to *McCuin*—there is no question that the plaintiffs could have sought judicial review under 42 U.S.C. 1395ff after presentment of a claim and exhaustion of the administrative process. See *Westchester Management Corp.*, 948 F.2d at 281-282 (the *Michigan Academy* methodology exception to *Ringer* "applies only when there is no other avenue of judicial review").

In *Bodimetric Health Services, Inc.* v. *Aetna Life & Casualty*, 903 F.2d 480 (7th Cir.), cert. denied, 111 S. Ct. 579 (1990), the court of appeals held that, because the

plaintiff could have sought review through the Medicare Act's administrative and judicial review process, that process was the exclusive means of obtaining judicial review. See *Bodimetric*, 903 F.2d at 486-487. That reasoning is entirely consistent with *Ringer* and the D.C. Circuit's decision in the present case.[5]

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

KENNETH W. STARR
Solicitor General

STUART M. GERSON
Assistant Attorney General

ANTHONY J. STEINMEYER
ROBERT M. LOEB
Attorneys

DECEMBER 1992

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[5] In dicta, the Seventh Circuit appeared to construe *Michigan Academy* as extending to any claim that cannot be remedied through the administrative process. See 903 F.2d at 486-487. It is far from clear that the Seventh Circuit would adhere to that approach in a case governed by the 1986 amendment. In any event, it was entirely possible for petitioners to obtain the result they sought—reversal of the carrier's decision to lower the reimbursement rate—through the administrative process. Consequently, even if the court of appeals had applied the Seventh Circuit's dicta, it would have required petitioners to present a claim and exhaust their administrative remedies.

No. 92-569

Supreme Court, U.S.
FILED
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IN THE

Supreme Court of the United States

OCTOBER TERM, 1992

NATIONAL KIDNEY PATIENTS ASSOCIATION, *et al.*,
Petitioners,

v.

LOUIS W. SULLIVAN, M.D.,
SECRETARY OF THE UNITED STATES DEPARTMENT
OF HEALTH AND HUMAN SERVICES, *et al.*,
Respondents.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

AMICUS CURIAE BRIEF OF

American Medical Association
American Academy of Dermatology
American Academy of Orthopaedic Surgeons
American College of Radiology
American College of Radiation Oncology
American Group Practice Association
American Psychiatric Association
American Psychological Association
American Society of Cataract and Refractive Surgery
American Society of Outpatient Surgeons
American Society of Ophthalmic Administrators
Association of Freestanding Radiation Oncology Centers
Federated Ambulatory Surgery Association
Group Health Association of America
Outpatient Ophthalmic Surgery Society
National Association of Diagnostic Services

IN SUPPORT OF THE PETITION

Patrick K. O'Hare*
Diane S. Millman
Joel I. Suldan
McDERMOTT, WILL & EMERY
1850 K Street, N.W., Suite 450
Washington, D.C. 20006-2296
(202) 887-8000
Attorneys for Amici Curiae
* *Counsel of Record*

Balmar Legal Publishing Services, Washington, D.C., (202) 682-9800

TABLE OF CONTENTS

	Page
TABLE OF AUTHORITIES	ii
INTEREST OF THE AMICI CURIAE	2
SUMMARY OF ARGUMENT	4
ARGUMENT	4
I. The D.C. Circuit's Decision Places Substantial, Inappropriate, And Unnecessary Obstacles In The Path Of Parties Seeking To Challenge The Validity Of Medicare Regulations And National Policies In The D.C. Circuit	7
II. It Is Crucial For Beneficiaries And Providers To Have Timely Access To The D.C. Circuit For Disputes Involving The Legality Of Medicare Policies Because The D.C. Circuit Is The Only Circuit In A Position To Issue Determinative National Rulings On These Issues	12
III. The D.C. Circuit's Decision Leaves Beneficiaries And Providers In An Untenable State Of Uncertainty That Can Only Be Resolved By This Court	15
CONCLUSION	17

TABLE OF AUTHORITIES

Cases	Page(s)
Abbey v. Sullivan, ___ F.2d ___, 1992 WL 238053 (2d Cir. September 28, 1992)	7
Abington Memorial Hosp. v. Heckler, 750 F.2d 242 (3d Cir. 1984), *cert. denied*, 474 U.S. 863 (1985)	13
American Lithotripsy Society v. Sullivan, 785 F. Supp. 1034 (D.D.C. 1992)	5, 10
American Society of Cataract & Refractive Surgery v. Sullivan, 772 F. Supp. 666 (D.D.C. 1991), *appeal docketed*	5
Bedford County Memorial Hosp. v. HHS, 769 F.2d 1017 (4th Cir.), *on remand*, 660 F. Supp. 23 (E.D. Va. 1985)	14
Bodimetric Health Services, Inc. v. Aetna Life & Casualty, 903 F.2d 480 (7th Cir.), *cert. denied*, 111 S. Ct. 579 (1990)	15
Bowen v. Michigan Academy of Family Physicians, 476 U.S. 667 (1986)	*passim*
Cardiac Monitoring Services, Inc. v. Blue Cross & Blue Shield of Arkansas, ___ F. Supp. ___, 1992 WL 314073 (E.D. Ark. Aug. 6, 1992)	15
DeSoto Gen. Hosp. v. Heckler, 766 F.2d 182 (5th Cir. 1985)	14
Georgetown Univ. Hosp. v. Bowen, 862 F.2d 323 (D.C. Cir. 1988)	12
Humana of Aurora, Inc. v. Heckler, 753 F.2d 1579 (10th Cir.), *cert. denied*, 474 U.S. 863 (1985)	14

Linoz v. Heckler, 800 F.2d 871 (9th Cir. 1986) . . 5

Lloyd Noland Hosp. & Clinic v. Heckler, 762 F.2d 1561 (11th Cir. 1985) 14

McCuin v. Secretary of Health & Human Services, 817 F.2d 161 (1st Cir. 1987) 15

McNary v. Haitian Refugee Center, Inc., 111 S. Ct. 888 (1991) 11, 12

Medics, Inc. v. Sullivan, 766 F. Supp. 47 (D.P.R. 1991), *aff'd sub nom. La Casa Del Convaleciente v. Sullivan*, 965 F.2d 1175 (1st Cir. 1992) 5

Menorah Medical Center v. Heckler, 768 F.2d 292 (8th Cir. 1985) 14

National Kidney Patients Association v. Sullivan, 958 F.2d 1127 (D.C. Cir. 1992), *petition for cert. filed* (Sept. 29, 1992) . . . . . *passim*

Outpatient Ophthalmic Surgery Society, Inc. v. Sullivan, jurisdictional ruling reported at [1991 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 38,981 (D.D.C. December 14, 1990), *decision on merits pending* 5, 14

PIA-Asheville, Inc. v. Bowen, 850 F.2d 739 (D.C. Cir. 1988) 12

Pulmocare Pharmacy, Inc. v. Sullivan, Medicare and Medicaid Guide (CCH) ¶ 40,387 (D. Or. June 12, 1992) 15

St. James Hosp. v. Heckler, 760 F.2d 1460 (7th Cir.), *cert. denied*, 474 U.S. 902 (1985) 14

St. Mary of Nazareth Hosp. Center v. Heckler, 760 F.2d 1311 (D.C. Cir. 1985) 12

Walter O. Boswell Memorial Hosp. v. Heckler, 749 F.2d 788 (D.C. Cir. 1984), *on remand*, 628 F. Supp. 1121 (D.D.C. 1985) 12, 14

Weinberger v. Salfi, 422 U.S. 749 (1975) 9

STATUTES AND REGULATIONS

20 C.F.R. Part 404, Subpart J 8

20 C.F.R. §404.967 8

20 C.F.R. §404.981 9

42 C.F.R. §405.807 . . . . . 7, 9

42 C.F.R. §405.820 8

42 C.F.R. §405.860 8

5 U.S.C. §551 *et seq.* 5

28 U.S.C. §1331 . . . . . *passim*

28 U.S.C. §1391 12

42 U.S.C. §405(g) . . . . . *passim*

42 U.S.C. §1395ff(b)(1)(C) . . . . . *passim*

42 U.S.C. §1395oo 12

53 Fed. Reg. 20023 (June 1, 1988) 8

Omnibus Budget Reconciliation Act of 1986, Section 9313(b) 6

OTHER AUTHORITIES

GAO Rep. No. HRD-90-18 (November 28, 1989) 8

HCFA Ruling 87-3, 52 Fed. Reg. 13873 (April 27, 1987) 14

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American Society of Ophthalmic Administrators
Association of Freestanding Radiation Oncology Centers
Federated Ambulatory Surgery Association
Group Health Association of America
Outpatient Ophthalmic Surgery Society
National Association of Diagnostic Services

IN SUPPORT OF THE PETITION

Pursuant to Rule 37.2 of the Rules of this Court, the associations named above submit this brief as *amici curiae* in support of the Petition for a Writ of Certiorari to the Court of Appeals for the District of Columbia Circuit filed by Petitioners, National Kidney Patients Association, *et al.*, on September 29, 1992. Consent to the filing of this brief has been granted by the parties.

INTEREST OF THE AMICI CURIAE

Medicare is the primary source of health insurance for America's elderly and disabled citizens. The program covers more than 35 million beneficiaries, at an annual cost to the federal government of approximately $145 billion.[1] The *amici curiae* are professional and trade associations whose members provide items or services to Medicare beneficiaries and who are entitled to payment from Medicare for such items and services.[2]

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[1] Part A of the program provides coverage primarily for inpatient hospital services. Part B authorizes payment for various medical services and supplies.

[2] The American Medical Association is the largest organization representing physicians in the United States, having approximately 280,000 members. The American Academy of Dermatology is a private, nonprofit medical specialty society with over 8,900 members and is the largest medical organization of dermatologists in the world. The American Academy of Orthopaedic Surgeons is the primary educational and professional organization of orthopaedic surgeons in the United States; its membership includes nearly 18,500 orthopaedic surgeons, including approximately 95% of the board-certified orthopaedic surgeons in the United States. The American College of Radiology is the principal organization of radiologists and medical radiation physicists in the United States, with more than 28,000 members. The American College of Radiation Oncology is a professional association of approximately 1,000 physicians and other professionals specializing in the use of radiation to treat cancer. The American Group Practice Association represents the vast majority of the nation's large, multispecialty medical group practices. The American Psychiatric Association is the nation's largest professional association of psychiatrists, with more than 35,000 members.

As such, *amici* have a strong interest in the fair, efficient administration of Medicare and in the ability of aggrieved providers of health care services and beneficiaries to obtain timely, effective judicial review of agency actions affecting the administration of the program.

Amici believe that these interests will be severely damaged if the decision of the D.C. Circuit at issue here is left intact. The potential consequences of the D.C. Circuit's decision are of such overriding importance to both Medicare beneficiaries and providers that the decision requires immediate review by this Court.

The American Psychological Association is the principal professional association of psychologists in the United States; it has more than 100,000 members, including the vast majority of doctoral-level psychologists. The American Society of Cataract and Refractive Surgery is a scientific and educational association of approximately 5,000 ophthalmologists who are specially interested in cataract/intraocular lens implantation surgery and corneal refractive surgery. The American Society of Outpatient Surgeons is a professional association of approximately 400 physicians, from a wide variety of specialty areas, who specialize in the performance of outpatient surgical procedures. The American Society of Ophthalmic Administrators is a professional organization of approximately 1,800 individuals dedicated to the improvement of medical practice management. The Association of Freestanding Radiation Oncology Centers is a trade association representing over 200 non-hospital providers of radiation therapy services. The Federated Ambulatory Surgery Association is a national membership organization of over 400 ambulatory surgery centers, representing approximately 2,000 physicians, nurses, and health administrators at these facilities. The Group Health Association of America is a national trade association representing 335 managed care companies, often referred to as health maintenance organizations ("HMOs"), which provide health care services to 28 million Americans, including 1.8 million Medicare beneficiaries. The Outpatient Ophthalmic Surgery Society is a professional society of approximately 800 ophthalmologists having a particular interest in the use of the outpatient setting. The National Association of Diagnostic Services is a nonprofit association of physiological laboratories and equipment suppliers that provide diagnostic imaging services, including ultrasound, mammography, and nuclear medicine services.

SUMMARY OF ARGUMENT

The D.C. Circuit's decision means that the legality of Medicare regulations and national policies may be adjudicated in that Circuit only after exhaustion of a lengthy, burdensome, and inevitably futile administrative review process. Not only will this decision result in a substantial waste of private, administrative, and judicial resources, it will, as a practical matter, entirely preclude *any* review in many cases and will make it impossible for trade and professional associations such as *amici* to obtain timely, consolidated review on behalf of all of their affected members. Moreover, even if other Circuits could be persuaded to adopt a different view, the resulting intercircuit conflict will make eventual review by this Court virtually inevitable, so that beneficiaries and providers who seek relief in other Circuits risk incurring substantial retroactive damages. The D.C. Circuit's decision will thus leave the Medicare program almost entirely insulated from effective judicial oversight.

ARGUMENT

In *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667 (1986) (hereafter "*Michigan Academy*"), this Court held that general federal question (28 U.S.C. §1331) jurisdiction is available for disputes involving the "method" by which amounts paid under the Medicare program are determined. Specifically, this Court made it clear that 42 U.S.C. §1395ff(b)(1)(C), which by its terms governs disputes concerning the "amount" of Medicare benefits, does not apply to disputes involving "the method by which such amounts are to be determined." *Michigan Academy*, 476 U.S. at 675. Under the principles set forth in *Michigan Academy*, while a dispute involving the "amount" of payment can only be brought in federal court after the administrative review process provided by 42 U.S.C. §1395ff(b)(1)(C) has been exhausted, "method" challenges may be brought directly to federal court under Section 1331.

Although most Medicare regulations have been implemented without challenge, the federal courts have relied on *Michigan Academy* on numerous occasions to correct agency actions that were found to be inconsistent with the Medicare statute or with the Administrative Procedure Act, 5 U.S.C. §551 *et seq.* *See, e.g., Linoz v. Heckler*, 800 F.2d 871 (9th Cir. 1986) (invalidating Medicare Carrier Manual provision that effectively denied reimbursement for ambulance services); *Medics, Inc. v. Sullivan*, 766 F. Supp. 47 (D.P.R. 1991), *aff'd sub nom. La Casa Del Convaleciente v. Sullivan*, 965 F.2d 1175 (1st Cir. 1992) (successful procedural challenge to agency's policy regarding payment for certain items of durable medical equipment); *American Lithotripsy Society v. Sullivan*, 785 F. Supp. 1034 (D.D.C. 1992) (enjoining implementation of the initial payment rate established by the agency for lithotripsy services); *American Society of Cataract & Refractive Surgery v. Sullivan*, 772 F. Supp. 666 (D.D.C. 1991), *appeal docketed* (enjoining agency's withdrawal of Medicare coverage for intraocular lenses that have not received full Food and Drug Administration approval). It is therefore crucial that beneficiaries and providers retain access to a forum where they can obtain timely national determinations of the legality of Medicare regulations and national policies.[3]

The D.C. Circuit's decision in *National Kidney Patients Association v. Sullivan*, 958 F.2d 1127 (D.C. Cir. 1992), *petition for cert. filed* (Sept. 29, 1992) (hereafter "*NKPA*"), effectively nullifies *Michigan Academy* by ruling that the federal courts no longer have jurisdiction to hear such "method" challenges under Section 1331. The D.C. Circuit rationalizes its departure from

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[3] The *amici curiae* associations have themselves brought several such challenges. *See, e.g., American Society of Cataract & Refractive Surgery v. Sullivan, supra*; *Outpatient Ophthalmic Surgery Society, Inc. v. Sullivan, jurisdictional ruling reported at* [1991 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 38,981 (D.D.C. December 14, 1990), *decision on merits pending.*

this Court's clear holding by claiming that Congress mandated this result when it enacted Section 9313(b) of the Omnibus Budget Reconciliation Act of 1986 (hereafter "the 1986 amendments"). According to the D.C. Circuit, the 1986 amendments, which *expanded* judicial review under 42 U.S.C. §405(g) of *individual* claims regarding the amount of benefits payable under Part B of the Medicare program, implicitly eliminated Section 1331 jurisdiction over broader challenges to the methods used to calculate benefit amounts, including challenges to the legality of Medicare regulations. As a result, the Circuit held, 42 U.S.C. § 405(g)—with its requirement for exhaustion of all administrative remedies—now represents the sole jurisdictional basis for these "method" challenges. The D.C. Circuit reached this conclusion even though such "method" challenges generally cannot be resolved through the administrative review process.

This Court's early review of the D.C. Circuit's decision is essential. The decision deprives Medicare beneficiaries and providers of timely access to the D.C. Circuit for the resolution of important disputes concerning the legality of Medicare regulations and national policies. This lack of access to the D.C. Circuit cannot be remedied by seeking relief in other Circuits, because the D.C. Circuit is the *only* Circuit in a position to issue definitive national determinations with respect to the legality of Medicare regulations and national policies. And even in cases where another Circuit might potentially be able to provide relief, the existence of the *NKPA* decision leaves Medicare beneficiaries and providers in an untenable state of uncertainty with respect to the appropriate route for challenging allegedly illegal Medicare regulations or national policies — uncertainty which will, as a practical matter, leave the Medicare program essentially free of judicial oversight.

I. The D.C. Circuit's Decision Places Substantial, Inappropriate, And Unnecessary Obstacles In The Path Of Parties Seeking To Challenge The Validity Of Medicare Regulations And National Policies In The D.C. Circuit.

By requiring exhaustion of the administrative review process even for "method" challenges, the D.C. Circuit's decision in *NKPA* places substantial — and utterly unnecessary — obstacles in the way of beneficiaries and providers seeking federal court review of illegal agency action. Indeed, as a practical matter, the D.C. Circuit's insistence that beneficiaries and providers exhaust the administrative review process before instituting suit will entirely preclude review in the D.C. Circuit in many cases.[4]

The burden imposed on individual claimants by the administrative review process mandated by the D.C. Circuit is substantial. Specifically, a beneficiary or supplier seeking to challenge an allegedly illegal Medicare regulation first must request that its carrier[5] "review" the amount paid by the carrier pursuant to the challenged regulation. *See* 42 C.F.R. §405.807. This step must be completed even though the carriers are bound

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[4] The Second Circuit has already decided to follow the D.C. Circuit's lead with respect to the jurisdictional issue involved here. In *Abbey v. Sullivan*, ___ F.2d ___, 1992 WL 238053 (2d Cir. September 28, 1992), the Second Circuit adopted the D.C. Circuit's jurisdictional analysis, essentially without further elaboration. The Second Circuit reached this conclusion even though the dispute in *Abbey* could have been resolved through the administrative appeals process. In other words, the case arguably did not involve a "method" dispute within the meaning of *Michigan Academy*, so that the Second Circuit did not need to address the question raised in *NKPA*. Nevertheless, in light of *Abbey*, the barriers to judicial review that *NKPA* created for the D.C. Circuit now appear to apply in the Second Circuit as well.

[5] Carriers are private insurance companies engaged by the Secretary of Health and Human Services to process Medicare Part B claims.

to pay claims in accordance with Medicare regulations and other policies established by the agency and there is consequently nothing for the carrier to "review."

After the carrier completes its "review," the beneficiary or provider must request a hearing before a hearing officer — who likewise has no authority to deviate from payment methodologies set forth in Medicare regulations. *See* 42 C.F.R. §§405.820, 405.860. Since carriers conduct in excess of 30,000 hearings per year, this stage of the proceedings can be quite lengthy. In the experience of the *amici curiae* associations, from the time an appeal is initiated until the time the hearing officer renders his decision is generally several months, and can be a year or more.

After the hearing officer renders his decision, the beneficiary or provider must then appeal that decision to an administrative law judge ("ALJ") within the Social Security Administration. The ALJ, however, is also powerless to overturn Medicare regulations. *See* 53 Fed. Reg. 20023-24 (June 1, 1988) (providing that Medicare Part B appeals will be heard by Social Security ALJs and governed by 20 C.F.R. Part 404, Subpart J). According to a report from the General Accounting Office, the average time between the date an on-the-record hearing is requested and the date the decision is finally rendered by an ALJ is 154 days. GAO Rep. No. HRD-90-18 (November 28, 1989).

Finally, the ALJ's decision must be presented to the Appeals Council of the Department of Health and Human Services, even though it too is bound by the Secretary's regulations and other determinations. *See* 20 C.F.R. §404.967. Review by the Appeals Council can likewise involve substantial delays. Still, under the D.C. Circuit's decision, federal court action could not be initiated until the Appeals Council has rendered its decision.[6]

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[6] After presenting their claims, aggrieved parties arguably could institute suit in federal court under 42 U.S.C. §§ 405(g), 1395ff(b)(1)(C) and request

This lengthy, repetitive process would have to be followed by *each* individual beneficiary or provider interested in obtaining relief from an allegedly illegal Medicare regulation or policy. Indeed, while claims could be grouped together, each beneficiary or provider would likely be required to pursue several *separate* appeals, since under the regulations the right to administrative review of a particular claim is lost unless an appeal is initiated within six months of the carrier's initial determination on that claim. 42 C.F.R. §405.807(c). Thus, to fully protect their rights, providers who regularly furnish services affected by a challenged regulation or policy would have to initiate a new appeal at least once every six months until the matter is finally resolved. Similarly, requests for judicial review of an Appeals Council decision must be filed within 60 days of that decision, 20 C.F.R. §404.981, so that a provider who wishes to fully preserve his rights may ultimately need to initiate multiple federal court actions on the identical issue. In any event, even if an individual beneficiary is able to surmount these hurdles, the barriers posed by the administrative review process make it virtually impossible for any of the *amici* to do what could have been done prior to the D.C. Circuit's decision in *NKPA* — file a single suit challenging the regulation or policy at issue on behalf of all of their members.[7]

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waiver of exhaustion of the administrative process on the ground that exhaustion would be futile. However, this Court has sanctioned waiver of the exhaustion requirement only under limited circumstances. Specifically, this Court has held that the "statutorily specified jurisdictional prerequisite" in 42 U.S.C. § 405(g) is "something more than simply a codification of the judicially developed doctrine of exhaustion, and may not be dispensed with merely by a judicial conclusion of futility." *Weinberger v. Salfi*, 422 U.S. 749, 766 (1975). Moreover, the federal courts have never sanctioned waiver in a case involving providers (as opposed to beneficiaries).

[7] It may be possible for an association to file a class action challenging the legality of a particular regulation; however, unless the court waives the requirement that administrative remedies be exhausted, such a suit likely could not be brought until several association members had completed the

In short, requiring beneficiaries and providers to proceed individually through this lengthy review process would deluge the carriers, the ALJs, and the Appeals Council with complaints they have no authority to redress, at substantial cost to both private litigants and the Medicare program. Indeed, just handling such appeals will inevitably cause delays in the review of individual claims for benefits, the only type of case for which the administrative review process was designed. The courts, too, will eventually be faced with a profusion of virtually identical cases instead of the efficient, consolidated approach permitted under *Michigan Academy*. Clearly, the route mapped out by the D.C. Circuit does not provide a practical means of obtaining judicial oversight of the Medicare program.

The issue is not merely one of time and expense. There are numerous situations where the Part B administrative review process will effectively preclude *any* judicial review of Medicare regulations and policies. For example, consider the factual circumstances underlying the case of *American Lithotripsy Society*, *supra*, in which an association challenged the initial payment rate established for lithotripsy services provided in ambulatory surgical centers ("ASCs").[8] The plaintiffs in that case argued that the Health Care Financing Administration ("HCFA"), which administers the Medicare program, employed a ratesetting methodology for which there was no support in the administrative record, and contended that the rate adopted by HCFA was inconsistent with the information supplied by the public commenters. The District Court agreed,

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entire administrative review process. Even then, nationwide relief would probably be unavailable, as membership in the class would likely be limited to those who had completed the administrative review process and who individually met the amount in controversy threshold for filing in federal court.

[8] Lithotripsy involves the use of sound waves, administered from outside the body, to pulverize kidney stones, allowing treatment of this condition without invasive surgery.

issuing an order that enjoined HCFA from implementing the challenged rates and that directed HCFA to pursue further administrative proceedings.

Such direct and timely review, however, would have been impossible under the principles set forth in *NKPA*. Rather, to secure review under *NKPA*, an individual ASC would have had to purchase and install a lithotripsy machine at a cost of $1 million or more; provide lithotripsy services to Medicare patients; file claims for these services with the carrier; receive payment for those claims at the rate established by HCFA; and exhaust all of the administrative appeals described above. Only then could the facility have brought its challenge to federal court. Clearly, it is unrealistic to expect effective judicial review of the agency's action to emerge from such a set of requirements. In fact, it is likely that an ASC faced with the rate for lithotripsy services initially established by HCFA would simply decline to provide those services to Medicare beneficiaries, rather than invest the time and expense that would be required to challenge the rate through the process mandated by *NKPA*.

Not only is the Part B administrative review process mandated by *NKPA* unwieldy and extremely burdensome, it is completely unavailable to some types of providers. For example, many health maintenance organizations participating in the Medicare program do not file claims for benefits on an ongoing basis with Medicare carriers; rather, they are paid directly by HCFA on the basis of a cost report filed annually. It appears that such entities could not meet the jurisdictional prerequisites for filing suit under 42 U.S.C. §§405(g), 1395ff(b), and there is no apparent alternative route to federal court available to them.

This Court addressed an analogous set of facts just last year in *McNary v. Haitian Refugee Center, Inc.*, 111 S. Ct. 888 (1991). The plaintiffs in *McNary* were a class of illegal aliens seeking amnesty under recent amendments to the federal im-

migration statute. They sought to contest the interpretation given to the amendments by the Immigration and Naturalization Service ("INS"). The INS took the position that the plaintiffs' challenge could only be heard following administrative review of individual claims for amnesty. This Court rejected the INS's arguments, holding that "if not allowed to pursue their claims in the District Court, respondents would not as a practical matter be able to obtain meaningful judicial review of their application denials or of their objections to INS procedures." *Id.* at 898. If the *NKPA* decision is allowed to stand, it is clear that, as in *McNary*, Medicare beneficiaries and providers "[will] not as a practical matter be able to obtain meaningful judicial review" of illegal agency action.

II. It Is Crucial For Beneficiaries And Providers To Have Timely Access To The D.C. Circuit For Disputes Involving The Legality Of Medicare Policies Because The D.C. Circuit Is The Only Circuit In A Position To Issue Determinative National Rulings On These Issues.

The D.C. Circuit's decision in *NKPA* is especially important because that Circuit has historically played a unique role in determining the legality of Medicare regulations and national policies. Cases brought under *Michigan Academy* as well as certain other types of Medicare cases can generally be brought either in the District of Columbia or in the district where the plaintiff resides. *See* 28 U.S.C. §1391; 42 U.S.C. §1395oo. As a result, the D.C. Circuit has had to intervene frequently to invalidate Medicare regulations. *See, e.g., Georgetown Univ. Hosp. v. Bowen*, 862 F.2d 323 (D.C. Cir. 1988) (invalidating Medicare regulation governing calculation of "hospital-specific rate" for inpatient hospital care); *PIA-Asheville, Inc. v. Bowen*, 850 F.2d 739 (D.C. Cir. 1988) (invalidating Medicare regulation governing reevaluation of assets following change of ownership); *St. Mary of Nazareth Hosp. Center v. Heckler*, 760 F.2d

1311 (D.C. Cir. 1985) (invalidating nationwide HCFA policy regarding method of apportioning costs between Medicare and non-Medicare patients); *Walter O. Boswell Memorial Hosp. v. Heckler*, 749 F.2d 788 (D.C. Cir. 1984), *on remand*, 628 F. Supp. 1121 (D.D.C. 1985) (invalidating regulation governing allocation of malpractice-related expenses).

Significantly, the D.C. Circuit is the only Circuit that is in a position to issue conclusive national rulings regarding the legality of a Medicare regulation or national policy. When a challenge to a Medicare regulation is brought in another Circuit and the regulation is determined to be invalid by that Circuit, HCFA has frequently "nonacquiesced" in the unfavorable decision, continuing to litigate the same issue in other Circuits. This process generally continues until some plaintiff or set of plaintiffs obtains a favorable decision from the D.C. Circuit. Only then is the matter finally resolved, since other potential litigants can then seek similar relief from the D.C. Circuit. Thus, definitive, nationally applicable rulings concerning the legality of Medicare regulations historically have been available only in the D.C. Circuit, a forum which *NKPA* makes virtually inaccessible.[9]

Probably the best example of the impact of such "nonacquiescence" in the context of the Medicare program involves the litigation over the so-called "1979 malpractice rule," in which numerous providers challenged a regulation reducing payments to hospitals for the cost of malpractice insurance and related expenses. HCFA continued to litigate this issue until it became clear that the agency would lose in the D.C. Circuit, at which point HCFA offered a settlement. *See Abington Memorial*

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[9] Not only does *NKPA* require exhaustion of administrative remedies before suit may be filed in the D.C. Circuit, under 42 U.S.C. § 405(g), the only jurisdictional basis for Part B cases that will remain if *NKPA* is upheld, suit must be filed in the district where the plaintiff resides or does business, entirely precluding access to the D.C. Circuit in many cases.

Hosp. v. Heckler, 750 F.2d 242 (3d Cir. 1984), *cert. denied*, 474 U.S. 863 (1985); *Bedford County Memorial Hosp. v. HHS*, 769 F.2d 1017 (4th Cir.), *on remand*, 660 F. Supp. 23 (E.D. Va. 1985); *DeSoto Gen. Hosp. v. Heckler*, 766 F.2d 182 (5th Cir. 1985); *St. James Hosp. v. Heckler*, 760 F.2d 1460 (7th Cir.), *cert. denied*, 474 U.S. 902 (1985); *Menorah Medical Center v. Heckler*, 768 F.2d 292 (8th Cir. 1985); *Humana of Aurora, Inc. v. Heckler*, 753 F.2d 1579 (10th Cir.), *cert. denied*, 474 U.S. 863 (1985); *Lloyd Noland Hosp. & Clinic v. Heckler*, 762 F.2d 1561 (11th Cir. 1985); *Walter O. Boswell Memorial Hosp., supra.*

Another example involves the series of cases known as the "labor/delivery room cases," in which hospitals challenged the way in which HCFA treated costs associated with labor and delivery rooms. Again, HCFA continued to litigate the issue until a definitive ruling adverse to HCFA was obtained in the D.C. Circuit; only at that point did HCFA abandon the fight and agree to apply the D.C. ruling to all pending cases. *See* HCFA Ruling 87-3, 52 Fed. Reg. 13873 (April 27, 1987).

Thus, by depriving Medicare beneficiaries and providers of health care services of timely access to the D.C. Circuit to challenge the validity of Medicare regulations and national policies, the D.C. Circuit has paved the way to duplicative legal challenges to the validity of Medicare regulations and national policies and has thereby struck a substantial blow against administrative and judicial efficiency and economy. Since challenges to the validity of Medicare regulations and national policies often raise complex issues and require judicial review of lengthy administrative records,[10] the excess litigation that will result from this decision will impose a substantial additional burden on the already busy dockets of the federal courts.

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[10] For example, the administrative record in *Outpatient Ophthalmic Surgery Society v. Sullivan, supra*, consists of more than 3,000 pages.

III. The D.C. Circuit's Decision Leaves Beneficiaries And Providers In An Untenable State Of Uncertainty That Can Only Be Resolved By This Court.

As Petitioners demonstrate, the D.C. Circuit's decision conflicts with the decisions of other Circuits.[11] *See* Pet. at 19. Nevertheless, beneficiaries and providers seeking to challenge a Medicare regulation or policy cannot reliably avoid the impact of the D.C. Circuit's decision by instituting suit in another Circuit.

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[11] The D.C. Circuit itself acknowledges this conflict. *See* Pet. App. at 15a. Moreover, the reasoning used by the D.C. Circuit (and, now, the Second Circuit) is implicitly inconsistent with that of the First and Seventh Circuits. The D.C. and Second Circuits have both held that, as the result of enactment of the 1986 amendments, the term "amount," as used in 42 U.S.C. § 1395ff(b)(1)(C), includes the method for determining the amount of benefits. These Circuits have therefore held that individuals seeking to mount "method" challenges must exhaust the administrative appeals process prescribed in this section before seeking review in federal court. Although the rulings of the D.C. Circuit and the Second Circuit came in cases arising under Part B of Medicare, the relevant statute now makes no distinction between Part A and Part B; accordingly, their rulings would appear to apply to Part A as well. On the other hand, the First and Seventh Circuits have rendered decisions indicating that the amount/method distinction made by *Michigan Academy* continues to be good law for Part A disputes. *See McCuin v. Secretary of Health & Human Services*, 817 F.2d 161, 165 (1st Cir. 1987); *Bodimetric Health Services, Inc. v. Aetna Life & Casualty*, 903 F.2d 480, 484-87 (7th Cir.), *cert. denied*, 111 S. Ct. 579 (1990). These decisions implicitly suggest that the term "amount" as used in Section 1395ff(b)(1)(C) does *not* include "method" challenges under either Part A or Part B. At least two District Court decisions rendered since the D.C. Circuit's decision in *NKPA* have recognized this intercircuit conflict. In *Pulmocare Pharmacy, Inc. v. Sullivan*, Medicare and Medicaid Guide (CCH) ¶ 40,387 at 31,600 (D. Or. June 12, 1992), the U.S. District Court for the District of Oregon rejected *NKPA*'s jurisdictional analysis; in *Cardiac Monitoring Services, Inc. v. Blue Cross & Blue Shield of Arkansas*, ___ F. Supp. ___, 1992 WL 314073 (E.D. Ark. Aug. 6, 1992), the District Court for the Eastern District of Arkansas accepted it.

More specifically, consider the outlook for a beneficiary or provider (or an association acting on behalf of its members) that, in reliance on *Michigan Academy*, brings suit challenging a Medicare regulation outside the D.C. Circuit under Section 1331. Assume that this plaintiff wins a favorable ruling in District Court on both the jurisdictional issue and the merits, and that the decision is upheld by the appropriate Court of Appeals. Supreme Court review of the appellate decision then becomes almost certain, given the unavoidable intercircuit conflict that will have emerged concerning the issue in *NKPA*.

Should this Court, in reviewing such a decision, then decide that the D.C. Circuit's position on the jurisdictional issue is correct, whatever relief may have been awarded at the Circuit level will be vacated. Moreover, and potentially more seriously, the beneficiary or provider that brought the original action could find itself liable for substantial retroactive payments. For example, as a result of the D.C. Circuit's decision in *NKPA*, petitioner Home Intensive Care now allegedly faces *retroactive* recoupment of $15 million that it received pursuant to the injunction awarded by the District Court. *See* Pet. App. at 2a. And while *NKPA* involves only one supplier located primarily in one carrier jurisdiction and involves only one relatively minor component of the Medicare program, other "method" challenges may involve substantially greater exposure for retroactive recoupments.

Until this Court definitively resolves the jurisdictional issue presented in NKPA, this risk of retroactive recoupment will be present any time a beneficiary, provider, or association relies on the principles of *Michigan Academy* to challenge a Medicare regulation or national policy, regardless of the Circuit in which such a challenge is brought. Consequently, the D.C. Circuit's position with regard to the continued vitality of *Michigan Academy* will, as a practical matter, have a *national* impact, dramatically increasing for parties throughout the

country the risks of challenging even the most serious violations of the Medicare statute or the Administrative Procedure Act. It is plainly unfair to expect Medicare beneficiaries and providers (and their organizational representatives) to absorb these risks indefinitely. It is therefore essential that this Court act promptly to set aside the D.C. Circuit's decision and ensure the availability of timely judicial review of regulations and other policies affecting the administration of the Medicare program.

CONCLUSION

For the reasons set forth above, the *amici curiae* respectfully request this Court to grant the Petition for a Writ of Certiorari.

Respectfully submitted,

Patrick K. O'Hare*
Diane S. Millman
Joel I. Suldan
McDERMOTT, WILL & EMERY
1850 K Street, N.W., Suite 450
Washington, D.C. 20006-2296
(202) 887-8000
Attorneys for Amici Curiae

* *Counsel of Record*

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IN THE
Supreme Court of the United States
OCTOBER TERM, 1992

NATIONAL KIDNEY PATIENTS ASSOCIATION, *et al.*,
Petitioners,

v.

LOUIS W. SULLIVAN, M.D., SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, AND WILLIAM L. ROPER, M.D., ADMINISTRATOR OF THE UNITED STATES HEALTH CARE FINANCING ADMINISTRATION,

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

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REPLY BRIEF OF PETITIONERS

JOEL I. KLEIN *
PAUL M. SMITH
RICHARD G. TARANTO
KLEIN, FARR, SMITH & TARANTO
2550 M Street, N.W.
Washington, D.C. 20037
(202) 775-0184

* *Counsel of Record*

WILSON - EPES PRINTING CO., INC. - 789-0096 - WASHINGTON, D.C. 20001

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TABLE OF AUTHORITIES

Cases

	Page
Abbey v. Sullivan, No. 92-6055, 1992 U.S. App. LEXIS (2d Cir. Sept. 28, 1992)	5
Bodimetric Health Servs., Inc. v. Aetna Life & Casualty, 903 F.2d 480 (7th Cir. 1990)	5, 6
Bowen v. Michigan Academy of Family Physicians, 476 U.S. 667 (1986)	1, 2, 4, 6
Heckler v. Ringer, 466 U.S. 602 (1984)	3, 4, 6
McCuin v. Secretary of HHS, 817 F.2d 161 (1st Cir. 1987)	5
McNary v. Haitian Refugee Center, Inc., 111 S. Ct. 888 (1991)	3
United States v. Erika, Inc., 456 U.S. 201 (1982)	2, 3, 4

Statutes

42 U.S.C. § 1395ff(b)(1)(C)	*passim*
§ 1395ff(b)(2)	5
§ 1395ff(b)(4)	4, 5

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REPLY BRIEF OF PETITIONERS

Respondents' brief in opposition is significant for what it fails to address. Petitioners here rely on this Court's holding in *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667, 675 (1986), that claims involving "methods" of reimbursement under Medicare are not covered by the statutory provision governing administrative and judicial review of "amounts" determinations, 42 U.S.C. § 1395ff(b)(1)(C), and thus may be brought directly to court. We also contend that this "amount/method" distinction was expressly incorporated into the statute after *Michigan Academy*. Respondents simply ignore these critical points.

Thus, without addressing this Court's actual reasoning in *Michigan Academy*, the Government argues that the Court in that case manufactured a non-statutory basis for judicial review solely in order to avoid the conclusion that basic Part B reimbursement methodologies are entirely unreviewable. They then contend that this decision was overruled *sub silentio* when Congress amended section 1395ff(b)(1)(C) to provide an alternative avenue to review—*i.e.*, by including Part B "amount" determinations among the actions that may be challenged under that section. This reasoning, like the Government's additional contention that there is no conflict in the circuits, does not withstand scrutiny.

1. When all is said and done, the fact remains that respondents and the court below have faulted petitioners for failing to follow a statutory exhaustion rule that does not apply to their claim. Thus, although respondents seek to recast *Michigan Academy*, the Court there flatly held that *no* provision in the statute, including section 1395ff(b)(1)(C) with its exhaustion rule for challenges to the "amount" of reimbursement, "speak[s] to challenges mounted against the *method* by which such amounts are to be determined rather than the *determinations* themselves." *Michigan Academy*, 476 U.S. at 675 (emphasis in original). This ruling was the linchpin of the Court's further conclusion that, while Congress had impliedly precluded judicial review of Part B "amount" claims by omitting them from section 1395ff(b)(1)(C) (*see United States v. Erika, Inc.*, 456 U.S. 201, 208 (1982)), it had not similarly precluded review of Part B "method" claims. 476 U.S. at 676.

The D.C. Circuit, in turn, acknowledged that petitioners' claim falls into the "method" category. Pet. App. 12a. It nevertheless held that they were required to comply with the very administrative exhaustion requirement that this Court has held to be inapplicable to this type of claim. It did so solely on the ground that section

1395ff(b)(1)(C) was broadened in 1986 to cover "amount" claims under Part B as well as Part A. *Ibid.*

Respondents now seek to uphold this anomalous reasoning by arguing that, after this amendment, there is no longer any need to recognize some other avenue for judicial review of any Part B claim. They ask the Court to conclude that all "method" claims, under Part A and Part B, are now covered by section 1395ff(b)(1)(C) and by the administrative exhaustion requirement previously recognized in *Heckler v. Ringer*, 466 U.S. 602 (1984). In so doing, however, they ignore entirely the Court's actual construction of the statutory scheme in *Michigan Academy*. Thus, although the potential absence of judicial review was certainly a background consideration in the Court's analysis in that case, the Court in fact concluded that the pre-1986 version of section 1395ff(b)(1)(C) did not apply to any "method" claims, including the Part A "method" claims that were never, under any theory, totally insulated from judicial review.[1]

Now that the same section has been amended to cover Part B "amount" claims, it makes no sense to say that this change magically transformed the provision into one covering "method" claims as well. To the contrary, the only fair reading of *Michigan Academy* is that the section never covered "method" claims even under Part A, and that its amendment to cover Part B went no further than

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[1] As *United States v. Erika, Inc.*, 456 U.S. 201 (1982), illustrates, the Court has not hesitated to bar judicial review of some types of administrative action where congressional intent was clear. The presumption favoring review comes into play in the absence of clear congressional intent to foreclose such review. *See, e.g., McNary v. Haitian Refugee Center, Inc.*, 111 S. Ct. 888, 896-99 (1991). Contrary to respondents' contentions (Br. in Opp. 10-11), nothing in *McNary* or any other decision of this Court stands for the converse proposition that direct judicial review should be denied where the claimants could instead have proceeded first through an administrative process that Congress did not intend to extend to their type of claim.

to equalize treatment of "amount" claims under both parts. This means that "method" claims under both parts are still entirely unaddressed by the review provisions in the statute, and therefore may be pursued directly in court under 28 U.S.C. § 1331.

Respondents' repeated reliance on *Ringer* simply misses the point. That case never even considered the "amount/method" distinction. Nor, of course, did it hold that claimants are required to exhaust administrative processes that do not apply to their particular claims. Two years later, in *Michigan Academy*, when the Court *did* consider and adopt the "amount/method" distinction, it then distinguished *Ringer* as an "amount" case and thus one where exhaustion was appropriately required. 476 U.S. at 677 n.7. In any event, to the extent that there is some tension between *Ringer* and the subsequent decision in *Michigan Academy*, that tension itself argues strongly for a grant of review in this case.

Certainly respondents point to nothing to suggest that Congress, in expanding the coverage of section 1395ff(b)(1)(C) to include Part B "amount" claims, intended to overrule the holding of *Michigan Academy* with respect to "method" claims. If Congress had wanted to do that, it could easily have amended the section to cover claims challenging payment methodologies. But it did not do so. On the contrary, the sequence of events in the legislative history makes clear that the proposal to include Part B "amount" claims under the section was drafted long before the decision in *Michigan Academy*, solely in order to overrule the Court's earlier determination in *Erika* that Part B "amount" claims could be pursued only with private carriers. *See* Pet. 16-17.

Indeed, far from repudiating the "amount/method" distinction, Congress expressly adopted it in the very same 1986 amendments. As described in the petition, Congress also amended section 1395ff(b)(4) to bar challenges to pre-1981 regulations or instructions relating to

the "*method* for determining the amount of payment under part B." *See* Pet. 17-18. This change expressly incorporated the new "method/amount" distinction first enunciated in *Michigan Academy*, while grandfathering some longstanding rules. The amendments, in turn, were described by a key sponsor as *strengthening* the rights recently recognized in *Michigan Academy*. Yet respondents do not even mention section 1395ff(b)(4) or this aspect of the legislative history. That omission further demonstrates that respondents lack a persuasive basis for arguing that the 1986 legislative changes somehow undercut this Court's ruling in *Michigan Academy*.

2. Respondents are equally unsuccessful in their effort to dismiss the clear conflict over these issues among the circuits. They acknowledge that in *McCuin v. Secretary of HHS*, 817 F.2d 161 (1st Cir. 1987), the court squarely held that *Michigan Academy* authorized immediate judicial review of a Part A payment methodology, without regard to the requirements of section 1395ff(b)(1)(C). Br. in Opp. 14. Since the 1986 amendments made the statutory treatment of Part B claims identical with the treatment of Part A claims, this decision is irreconcilable with the decision below and with the recent ruling of the Second Circuit in *Abbey v. Sullivan*, No. 92-6055, 1992 U.S. App. LEXIS (2d Cir. Sept. 28, 1992) (also dealing with a Part B claim).

While disagreeing with *McCuin*, respondents suggest that it is distinguishable because the plaintiff there would otherwise have been denied all review, having failed to satisfy the amount-in-controversy requirement under section 1395ff(b)(1)(C), (2). Br. in Opp. 14. Yet nothing in the First Circuit's analysis indicates that it was relying on this factor. The court simply held that, after *Michigan Academy*, "method" claims under Part A (like those under Part B) may be brought directly to court.

Respondents also acknowledge that *dicta* in *Bodimetric Health Servs., Inc. v. Aetna Life & Casualty*, 903 F.2d

480 (7th Cir. 1990), support the continued applicability of *Michigan Academy* to Part A "method" claims. Br. in Opp. 15 n.5. They argue that the Seventh Circuit might not "adhere to that approach in a [Part A] case governed by the 1986 amendment." *Ibid.* But this assertion is inexplicable, because, as noted above, the 1986 amendment did not affect the treatment of Part A claims at all. In fact, there is every reason to expect that the Seventh Circuit will continue to recognize that Part A "method" claims (and, based on the same analysis, Part B "method" claims as well) are not covered by the administrative review process and may therefore be litigated in court under *Michigan Academy*.

The reason for this conflict among the circuits is not difficult to discern. As the D.C. Circuit here acknowledged, there is an apparent tension between *Michigan Academy* and the Court's prior line of cases culminating in *Ringer*. *See* Pet. App. 6a-7a. The Government here glosses over this problem by disregarding the Court's statutory analysis in *Michigan Academy* and arguing that the case was inadvertently overruled by Congress through the enactment of an amendment that is irrelevant to that statutory analysis. But the need for clarification of this Court's prior decisions remains glaringly apparent.

CONCLUSION

The petition should be granted.

Respectfully submitted,

JOEL I. KLEIN *
PAUL M. SMITH
RICHARD G. TARANTO
KLEIN, FARR, SMITH & TARANTO
2550 M Street, N.W.
Washington, D.C. 20037
(202) 775-0184

* *Counsel of Record*